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**Methods for developing and evaluating randomised controlled trials of complex interventions : case study of stroke secondary prevention**

Redfern, Judith Marion

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**METHODS FOR DEVELOPING AND EVALUATING  
RANDOMISED CONTROLLED TRIALS OF  
COMPLEX INTERVENTIONS – CASE STUDY OF  
STROKE SECONDARY PREVENTION**

**THESIS**

Presented for the

**DEGREE**

of

**DOCTOR OF PHILOSOPHY**

by

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Division of Health & Social Care Research

Guy's, King's & St Thomas' School of Medicine

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2007





**Student declaration**

I confirm that the work presented in this thesis is my own and has not been previously submitted for a degree or any other qualification at this University or another institution.

Signed: Frédéric Redel

Date: 19/01/07

## ABSTRACT

The UK Medical Research Council's Framework for developing complex public health interventions outlines distinct methodological phases. This thesis explores application of the first four phases (theoretical, modelling, exploratory trial, definitive RCT) in developing a novel intervention to reduce stroke recurrence.

An ethnographic approach was used entailing: in-depth interviews with stroke patients; observations in stroke clinics; participant observation; diaries; informal discussion with staff; in-depth interviews with key informants.

The theoretical phase was used to conduct empirical research into stroke secondary prevention. Important considerations for intervention development were uncovered. According to The Framework, these findings should have been used to define intervention components. In practice, theoretical findings were used as much in legitimising pre-defined research ideas as in defining them. Analysis of the modelling phase revealed that intervention design was influenced by 'interference', that is social, political and economic factors (including skill mix, priorities of the research team, resource constraints, time constraints and what could feasibly be evaluated using RCT methods). The exploratory trial was used to pilot test the intervention and refine trial methods but did not specifically follow Framework recommendations. In the definitive RCT, despite adhering to Framework recommendations, the intervention was not delivered as intended. Problems emerged relating to trial process, intervention implementation and environmental changes. While these may influence trial outcomes, interview data suggested that patients valued the intervention as an information resource, for promoting continuity and as a tool for empowering them to manage their own risk factors.

This thesis critiques The Framework as a tool for guiding research and improving interpretation of RCT outcomes. ‘Interference’ and problems of implementation are likely to be as important as theoretical work in influencing RCT outcomes. Process evaluation using ethnographic methods embedded within the RCT may help in interpreting trial outcomes but conflict between the two research paradigms cannot be ignored.

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## **List of Abbreviations**

BHS	British Hypertension Society
GP	General practitioner
HSR	Health services research
KCL	King's College London
MRC	UK Medical Research Council
NSF	National Service Framework for Older People
RCP	UK Royal College of Physicians
RCT	Randomised controlled trial
SLSR	South London Stroke Register
TIA	Transient ischaemic attack
WHO	World Health Organisation



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# Chapter 1. Introduction

## 1.1. Background to the thesis

I first became interested in methods for developing ‘complex interventions’ through my work on the Stop Stroke study, which began in 1999. My involvement in Stop Stroke included conducting a series of research studies into current practice and into patient and professional understanding of stroke secondary prevention. It was anticipated that this research would inform the development of a new complex intervention to prevent stroke recurrence, which would subsequently be evaluated in a randomised controlled trial (RCT). A year into the study the UK Medical Research Council (MRC) published a framework for developing and evaluating complex interventions using RCT methods.<sup>1</sup> Although the Stop Stroke study was already in progress, from that point on we (the other study investigators and I) began to cite ‘The Framework’ when describing our approach to intervention development, stating that it had guided the research process.

Over the past six years The MRC Framework for complex interventions has become increasingly popular. By 2004 presentation of a conference paper discussing The Framework would guarantee an enthusiastic audience.<sup>2</sup> To date, The Framework has been cited in over 160 peer-reviewed publications including being used to support methods of intervention development which pre-dated its publication,<sup>3</sup> and has been used particularly to support the incorporation of qualitative or mixed methods into research designs.<sup>4,5</sup> Yet The Framework is not universally accepted and its subsequent publication in the British Medical Journal<sup>6</sup> rekindled a debate over the appropriateness of RCT methods for evaluating so called ‘complex’ interventions.<sup>7-9</sup>

As I will discuss in Chapter 2, this was not the first or most detailed framework to be published on the development of health services research (HSR) interventions, nor was



it the first time researchers had recommended applying the principles of evidence based medicine outside of the usual clinical context. As a consequence I was interested to find out why this framework in particular (which at first glance appeared to provide little practical guidance for our research), had sparked so much interest and how it could be applied in practice. Using qualitative methods embedded within a RCT, in this thesis I use Stop Stroke as a case study with which to investigate the application of the MRC Framework.

## **1.2. Introduction to Stop Stroke, a case study**

In the next section I provide an overview of the Stop Stroke study, starting with an introduction to stroke disease, followed by a discussion of secondary prevention strategies for stroke and an outline of the Stop Stroke intervention.

### *1.2.1. What is a stroke?*

The World Health Organisation define as a stroke as ‘focal or global neurological impairment of sudden onset and lasting more than 24 hours’.<sup>10</sup> Strokes can be distinguished from other types of neurological impairment in that the impairment is considered to be of vascular origin.<sup>11</sup> Strokes can be divided into three distinct subtypes, cerebral infarction (due to a blood clot) intracerebral haemorrhage (bleeding inside the brain) and subarachnoid haemorrhage (bleeding between the brain and the covering membrane).<sup>12</sup> Cerebral infarction can be further classified according to pathological assumptions,<sup>13</sup> or the resulting clinical impairment.<sup>14</sup> Neurological symptoms of vascular origin lasting less than 24 hours with no lasting impairment are distinguished from stroke and defined as mini-strokes or transient ischaemic attack (TIA).

The consequences of stroke are varied but commonly include physical and psychological impairments including: weakness, stiffness or impairment of limbs; incontinence; cognitive impairment (including memory loss or problems with sight); difficulty with speech and language (dysphasia and dysarthria); pain; fatigue and problems with sleep; and mood changes (including anxiety and depression).<sup>11</sup>

### *1.2.1. The impact of stroke*

Stroke is the most common cause of adult disability and third most common cause of death in the developed world.<sup>15</sup> Stroke affects mainly older people with the majority (just under three-quarters) of cases occurring in people over the age of 65 years.<sup>16,17</sup> Estimates of the recurrence risk vary depending on how recurrence is defined.<sup>18,19</sup> Recent estimates suggest that the risk of recurrence within three months of an incident stroke is approximately 18%<sup>18</sup> and the risk of any major vascular event within 10 years after a stroke or TIA may be as high 54%.<sup>20</sup>

Estimates of stroke impact and recovery vary depending on how the consequences of stroke are defined and measured.<sup>11</sup> A recent study of stroke survivors in South London estimated that only two fifths were independent in activities of daily living one year post stroke and that just under half experienced some form of handicap<sup>i</sup> as a result of stroke related impairment or disability.<sup>22</sup> In the Royal College of Physicians of England (RCP) Sentinel Audit of Stroke, just over a fifth of previously independent stroke survivors were discharged to institutional (residential or hospital) accommodation.<sup>23</sup> However, the majority of stroke survivors with disabilities live in the community,

---

<sup>i</sup> Definitions of disability and handicap were defined used World Health Organisation classifications where handicap is defined as 'a disadvantage for a given individual, resulting from an impairment or a disability, that limits or prevents the fulfilment of a role that is normal (depending on age, sex, social and cultural factors) for that individual.'<sup>21</sup> In this study disability was measured using the Barthel Index and handicap measured using the Frenchay Activities Index.



relying on the support of informal carers such as family and friends.<sup>24,25</sup> Thus families and carers for people with stroke may also be affected by the consequences.

Stroke is costly both at an individual level and for wider society and with the increasing older population, stroke prevention is becoming an important public health priority worldwide. In the UK this is reflected in recent public health policy documents such the National Service Framework for Older People,<sup>26</sup> as well as in the development of guidelines on treatment and prevention.<sup>27</sup>

### *1.2.2. Stroke prevention and secondary prevention*

The causes of stroke are complex with many different factors independently associated with higher rates of stroke. These include clinical factors (high blood pressure, diabetes, high cholesterol, coronary heart disease and atrial fibrillation), lifestyle factors (smoking, diet, alcohol consumption and obesity), genetic factors (ethnicity, rare blood disorders), social and demographic factors (age, poverty, ethnicity), some of which are amenable to health service intervention, some of which are more appropriately addressed through policy<sup>19</sup> and some of which are not amenable to change at all. Prevention of first ever stroke (primary prevention) is known to be particularly difficult to achieve through health service intervention.<sup>28,29</sup> Those who have had one stroke are at particularly high risk (15-fold increased risk) compared to the general population<sup>30</sup> and it is thought that subsequent strokes may cause additional if not more severe damage to the brain, leading to death, additional disability or dependence on health services.<sup>31,32</sup> Consequently researchers have recommended that health service attention be redirected to target those most at risk such as preventing recurrent stroke (secondary prevention).<sup>29</sup> In 2000 The RCP produced evidence-based guidelines for stroke management (later updated in 2002 and 2004).<sup>27,33</sup> Recommended strategies for achieving optimal

secondary prevention include keeping blood pressure, cholesterol and body weight within clinically defined ‘safe limits’ (through taking medication, restricting food intake and increasing levels of exercise), keeping blood sugar levels controlled in those diagnosed with diabetes, taking antithrombotic medications (such as aspirin and warfarin) to prevent blood clots from forming, giving up smoking and moderating the amount of alcohol consumed. These strategies are not dissimilar to those recommended for prevention of other vascular diseases or for primary stroke prevention. Existing epidemiological studies have demonstrated inadequacies in secondary prevention management. For example research in South London conducted prior to the Stop Stroke study demonstrated inadequacies in prescribing of antithrombotic and anti-hypertensive medication. A quarter of those appropriate for aspirin, a third of those appropriate for anti-hypertensive medication and two thirds of those appropriate for warfarin were found to be inadequately treated three months post stroke.<sup>34</sup> Some studies conducted since the start of Stop Stroke have demonstrated improved management over time.<sup>35,36</sup> However, most also report that inadequacies remain in relation to medication prescribing and adherence to medication or lifestyle recommendations.<sup>35-41</sup>

### *1.2.3. The Stop Stroke intervention*

‘Stop Stroke’ is part of a project to improve secondary prevention management after stroke. The study started with an investigation of current secondary prevention to inform development of an intervention (as explained in section 1.1.). The intervention was subsequently tested in a pilot evaluation to investigate the feasibility of implementing the intervention and is currently being evaluated for efficacy in a cluster RCT involving 120 general practices. Key outcomes include blood pressure control,



smoking cessation and aspirin use. A detailed description of the intervention is presented in Chapter 7.

### **1.3. Aims, objectives and organisation of the thesis**

Using Stop Stroke as a case study, this thesis investigates the process of using the MRC Framework to develop and evaluate a complex intervention. A second aim is to explore the use of qualitative methods in understanding and enhancing RCT evaluations. Social studies of science and technology have demonstrated the importance of structural, cultural, political and economic influences in the construction of scientific knowledge, including the development of clinical evidence.<sup>42,43</sup> Authors have demonstrated how such influences may bias our understanding of the efficacy of pharmaceutical therapies.<sup>44-46</sup> Less is known about how social, economic or political processes influence the development of evidence in relation to complex health and social interventions. This thesis uses an ethnographic approach, incorporating a range of qualitative methods to investigate the application of The Framework in this context and aims to address the following objectives:

- To develop a clearer definition of the concept of a complex intervention (Chapter 2)
- To critically review the literature on methods for developing and evaluating complex interventions, including the use of RCTs and qualitative methods (Chapter 2)
- To systematically review the methods used to develop and evaluate complex interventions in stroke care (Chapter 3)
- To investigate the relationship between theoretical and methodological rigour in intervention development and study outcome (Chapter 3)

- To investigate the use of in-depth interview methods in intervention development (Chapter 5)
- To investigate the use of non-participant observation methods in intervention development (Chapter 6)
- To investigate the application of the MRC Framework in complex intervention development (Chapters 5, 6 and 7)
- To investigate the application of the MRC Framework in RCT evaluation of complex interventions (Chapter 8)
- To investigate the use of ethnographic methods, embedded within a RCT, to evaluate intervention implementation (Chapter 8)
- To investigate the use of qualitative methods alongside a RCT to understand outcomes (Chapter 9)
- To discuss the practical, ethical, clinical and social implications of the findings from Chapters 2-8 for complex intervention development (Chapter 10).

## **Chapter 2. Challenges for complex intervention development**

This chapter begins with a discussion of what is meant by the term ‘complex intervention’ and how complexity has been defined in the literature. An overview of methods for developing and evaluating complex interventions is presented including key arguments for and against the use of RCTs in this context. The discussion includes an introduction to the MRC Framework and other models of health care evaluation and an introduction to the use of qualitative methods in the context of complex intervention development.

### **2.1. What are complex health interventions?**

Although many clinical interventions could in one way or another be defined as complex, an exact definition of a ‘complex intervention’ within the public health/HSR context is unclear. This is illustrated by the rather vague MRC definition:

‘The greater the difficulty in defining precisely what exactly are the active ingredients of an intervention and how they relate to each other, the greater the likelihood that you are dealing with a complex intervention.’<sup>i</sup>(p1)

Within public health and HSR use of the term is relatively new. To develop a clearer definition I conducted a literature search<sup>ii</sup> on how the term ‘complex intervention’ had been defined by authors in published reports. The search identified 154 reports (including articles, editorials and letters), 58 of which discussed complicated

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<sup>ii</sup> In September 2005 I conducted a literature search using two online databases (Science Citation Index and Social Science Citation Index) via Web of Science, with the words ‘complex intervention’ entered as a key phrase. All types of report (letters, editorials, review articles and original research articles) were included provided that the term ‘complex’ was used to refer to health interventions. Studies were categorised according to whether they focused on pharmacological therapies, surgical interventions or other health services or public health interventions. Articles referring to health services and public health interventions were retrieved and the way the authors had defined ‘complex’ further coded into categories listed above.

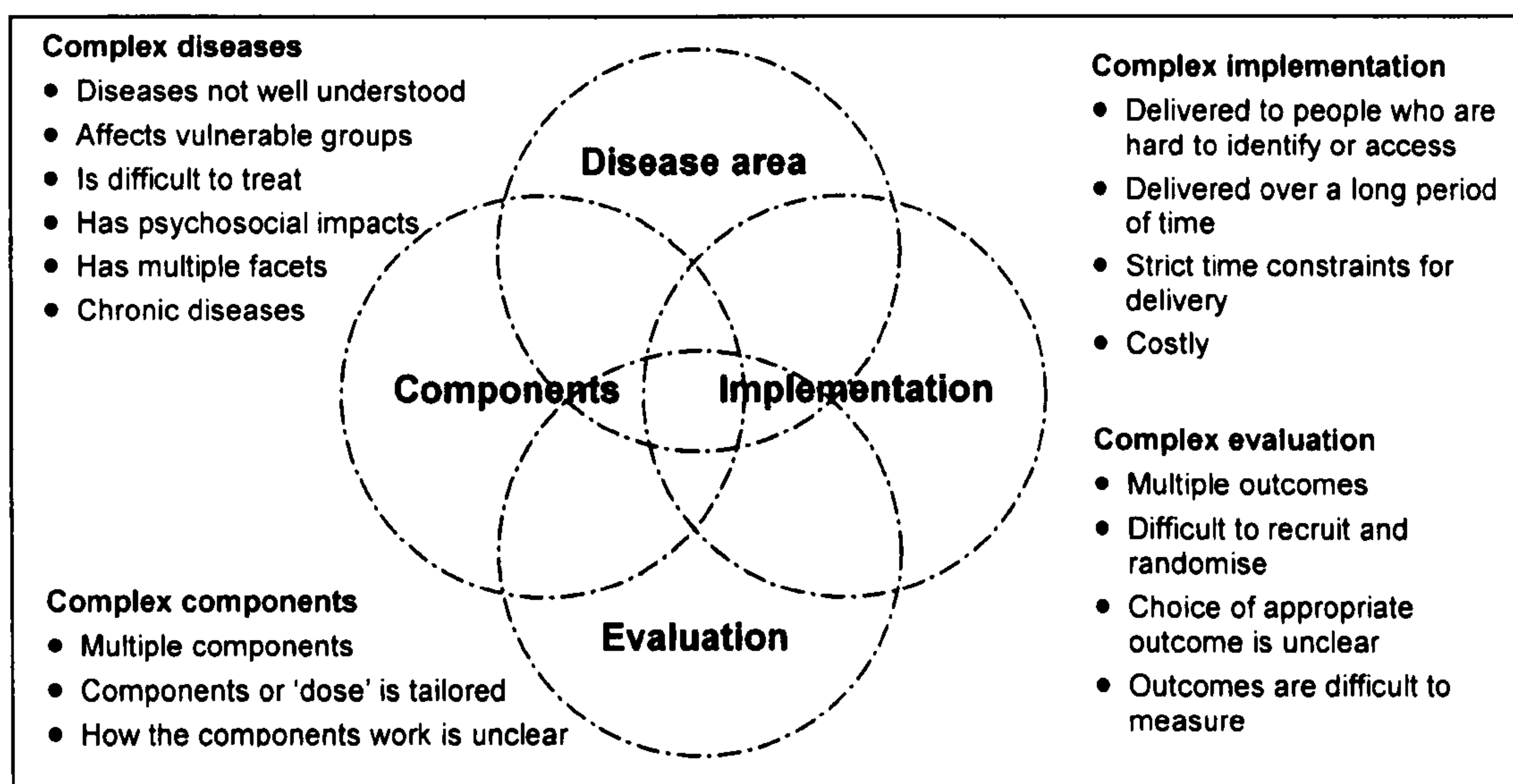


pharmacological or surgical procedures not relevant in this context and 98 of which were relevant to this thesis. As in the MRC Framework, many authors did not provide an explicit definition, characterising complexity by what it was not rather than what it was (in other words simple interventions were defined and complex interventions assumed to be those which did not fit these criteria) and some authors suggested that any non-pharmacological intervention was complex. The more specific characteristics of complex interventions relate to four main themes including disease group, the components of the intervention, the way the intervention was implemented or the methods used in evaluation. There were some contradictions between authors over these characteristics. For example in some reports the authors described educational interventions as being complex;<sup>47-50</sup> in others, educational interventions were only defined as complex if the education component was accompanied by other components such as counselling, decision support, feedback, emotional support, or coordination.<sup>51-55</sup> In some reports educational interventions were considered complex if there was something about the method of delivery that was complex; for example, if the education was delivered using multiple strategies or if it was delivered using novel methods of delivery such as a peer-led or advocate-led educational interventions.<sup>56,57</sup> By contrast, in one report educational interventions were cited specifically as examples of interventions, which were non-complex.<sup>58</sup> To clarify for the purposes of this thesis I would propose that complexity can be more easily understood as comprising a number of different layers (Figure 1).

All interventions, whether single or multiple component, whether tailored or standardised can be seen as complex to a certain extent. However, for some types of intervention, complexity refers to only one layer (such as being targeted at a complex disease group) while others have multiple layers (targeted at a complex disease group



**Figure 1. Layers of complexity in complex interventions.**



and have multiple components which are therefore difficult to implement and evaluate). Depending on the type of intervention and the different layers of complexity, the challenges for development and evaluation of interventions are likely to be very different. It is these challenges that will be investigated in this thesis.

## 2.2. Methods for developing and evaluating complex interventions

With the emergence of evidence-based healthcare in the 1980s and 90s there have been calls over the past decade, for clinical interventions to be evaluated in terms of efficacy, cost and subsequently, the strengthening of methods to achieve this.<sup>59-61</sup>

Different methods exist for investigating and evaluating health care.<sup>62</sup> Current epidemiological thought proposes a hierarchy of evidence for determining the efficacy of an intervention, at the top of which (the 'gold standard') is the RCT, or meta-analyses of multiple RCTs.<sup>63,64</sup>

### *2.2.1. Randomised controlled trials*

The RCT as we understand it today has evolved predominantly over the past 50 years<sup>65</sup> although there was evidence of comparative studies of medicinal treatments as early as the 18<sup>th</sup> Century.<sup>66,67</sup> Pocock defines a trial as ‘a planned experiment to elucidate the most appropriate treatment of future patients with a given medical condition’ (p1)<sup>65</sup>. Results are used from a sample of patients to make inferences about how treatment should be conducted in a wide population.

A RCT in its most basic sense can be described as a prospective experimental study involving random allocation of participants to one of two (or more) groups, to compare the effect of the treatment against no treatment or an appropriate alternative.<sup>62</sup> Rothman and Greenland define ‘clinical trials’ as particular types of experiment involving people who already have a defined disease.<sup>62</sup> They distinguish the clinical trial from other types of epidemiological experiment in which there is absence of disease (those involving the general population, which they term ‘field trials’), or those in which the intervention is delivered on a community-wide basis rather than an individual basis (termed ‘community intervention trials’).

Regardless of where the experiment takes place or who the participants are, one of the basic assumptions of the RCT method is that it is possible to isolate the impact of the intervention on a given outcome. In a typical laboratory experiment, this may be relatively straightforward since, it is possible to control the environment in which an interaction takes place. However, in the context of clinical trials (involving human participants), controlling the environment is more complicated and it is therefore more difficult to isolate the impact of the intervention alone.<sup>68</sup> Using a comparison or control group and allocating subjects to the groups in a random fashion were methods designed to overcome these problems. Studies which incorporate only one of these methods, for



example those that do not use randomisation or use before and after comparisons with no appropriate control group, are not thought to properly fulfil the methodological requirements for producing robust unbiased research evidence and are sometimes termed ‘quasi experimental’<sup>69</sup> (in Rothman & Greenland, p68<sup>62</sup>).

### *2.2.2. Randomised controlled trials and complex interventions*

RCTs have mostly been used within the pharmaceutical industry to evaluate the efficacy of new drugs, as a result of concerns for patient safety<sup>iii</sup>. However, since the 1970s, RCT testing has also been applied to existing therapies (p29)<sup>63</sup> and is a pre-requisite for development of other types of clinical intervention including non-pharmacological procedures, technologies and devices.<sup>71</sup> As Oakley has illustrated, the experimental method also has a long history in the social sciences particularly in the fields of psychology and sociology,<sup>72-74</sup> and in the past decade there have been calls to strengthen the ‘evidence base’ for complex interventions, for example in areas such as rehabilitation.<sup>75</sup> Such calls reflect broader changes in relation to the construction of medical knowledge, that is the increased contribution of academia to medicine and the assumption that knowledge should be based on unbiased evaluations of treatments rather than subjective estimations of impact or ‘good intentions’.<sup>42,76</sup>

However, there has been considerable debate in the literature over the appropriateness of using RCT methods in this context.<sup>77-79</sup> Some argue that the only method of establishing evidence of the efficacy of an intervention is through the use of RCT

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<sup>iii</sup> Although policies for drug regulation have evolved throughout the 20<sup>th</sup>-21<sup>st</sup> centuries, recent developments have largely evolved in response to drug related tragedies such as the thalidomide disaster in the 1960s. Such tragedies prompted the regulating bodies at the time (the Food and Drugs Administration, FDA in the US and the Committee on the Safety of Drugs, CSD in the UK) to introduce recommendations to ensure that all drugs were properly tested and safe before marketing.<sup>70</sup>

methods<sup>73</sup> and that concerns for patient safety apply equally to public health and social interventions.<sup>76</sup> Others, including the World Health Organisation (WHO), disagree:

‘RCTs are inappropriate for evaluating health promotion, they are often misleading and unnecessarily expensive’<sup>80</sup> (p5).

While some of the arguments clearly stem from ‘paradigm wars’ within health and social sciences (between those who believe in a positivist rather than a constructivist approach, or between those who prefer the use of a particular type of evaluation method),<sup>81,82</sup> much of this debate probably also stems from a lack of definition of the meaning of complexity. While it may be relatively straightforward to use RCT methods to assess the impact of a simple educational intervention (such as a patient leaflet delivered within a hospital setting), assessment may prove more difficult if the intervention has multiple non-standardised components, is delivered at a community-level or aims to have an impact on something more difficult to measure such as improved social capital.<sup>83</sup> Those conducting social studies of evidence-based medicine have argued that forcing non-pharmacological interventions to be evaluated using RCT methods ensures that only those interventions amenable to RCT evaluation (which excludes many population based or social interventions) will be researched.<sup>84</sup>

For a number of reasons it is difficult to evaluate some types of complex interventions using the experimental method. These will now be outlined.

#### *2.2.2.1. Difficult to randomise participants*

In the case of complex interventions, randomised allocation of participants or identification of suitable controls can sometimes prove difficult, particularly where the intervention is designed to influence individual outcomes via organisational or community change. In such instances it would not be possible to randomise individual participants. Special procedures such as ‘cluster randomisation’ have been developed to



allow for group allocation in statistical analyses.<sup>85</sup> There have been some examples of novel community interventions in health care which have incorporated such cluster designs.<sup>57,86</sup> However, although specialist statistical techniques may be able to compensate for some difficulties of evaluation, they cannot address problems such as what to do if an appropriate control community or group cannot be found, (for example in evaluating national-level interventions such as media campaigns).

#### *2.2.2.2. Difficult to identify the active ingredients*

Some health promotion specialists argue that RCT methods are often inappropriate for evaluating complex interventions that comprise multiple components since it is difficult to identify which components of the intervention are the ‘active ingredients.’<sup>87,88</sup> Certain types of complex intervention such as counselling, cognitive behavioural therapy or educational interventions often require the intervention to be tailored to the individual participant, meaning that the active part of the intervention is not standardised. Thus it is difficult to know what dose is required to achieve a given outcome when generalising research findings to a wider population. It is argued that since complex interventions often incorporate multiple components, the intervention becomes a ‘black box’ such that, when final outcomes are measured it is not possible to interpret which parts of the intervention have been successful.<sup>87</sup> However, others suggest that multiple components and tailoring of individual components are not necessarily a problem for applying RCT methods since in such cases the package or intervention concept remains standardised rather than the components themselves.<sup>7</sup>

### *2.2.2.3. Difficult to evaluate success*

Both Tones and Nutbeam argue that choice of outcome measures used to evaluate success in complex intervention trials has not always been appropriate.<sup>8,87</sup> They argue that health promotion interventions often aim to change outcomes over the longer term (up to 10 years or more) and although theoretically not a problem, practically it may be difficult to conduct a trial for such a long time. Large numbers of participants would be likely to drop out making it difficult to recruit required numbers and difficult to interpret the results. Nutbeam also argues that in many cases shorter-term process outcomes cannot be appropriately measured using the usual quantitative indicators of success.<sup>87</sup> Others argue that multi-disciplinary interventions also pose cultural and organisational challenges for implementation that make the conduct of RCTs difficult over and above the complexity of the intervention itself.<sup>77,89</sup> For example, the different agendas of researchers, managers and practitioners<sup>90</sup> or the different epistemological orientations and status of researchers from different disciplines.<sup>89</sup>

## **2.3. The MRC Framework for complex intervention development.**

In order to improve our understanding of complex interventions, the MRC published a framework for guiding development and evaluation.<sup>1,6iv</sup> The Framework aims to guide intervention development by breaking down the process into five phases, paralleling those used in the pharmaceutical industry in developing drug therapies (Figure 2).

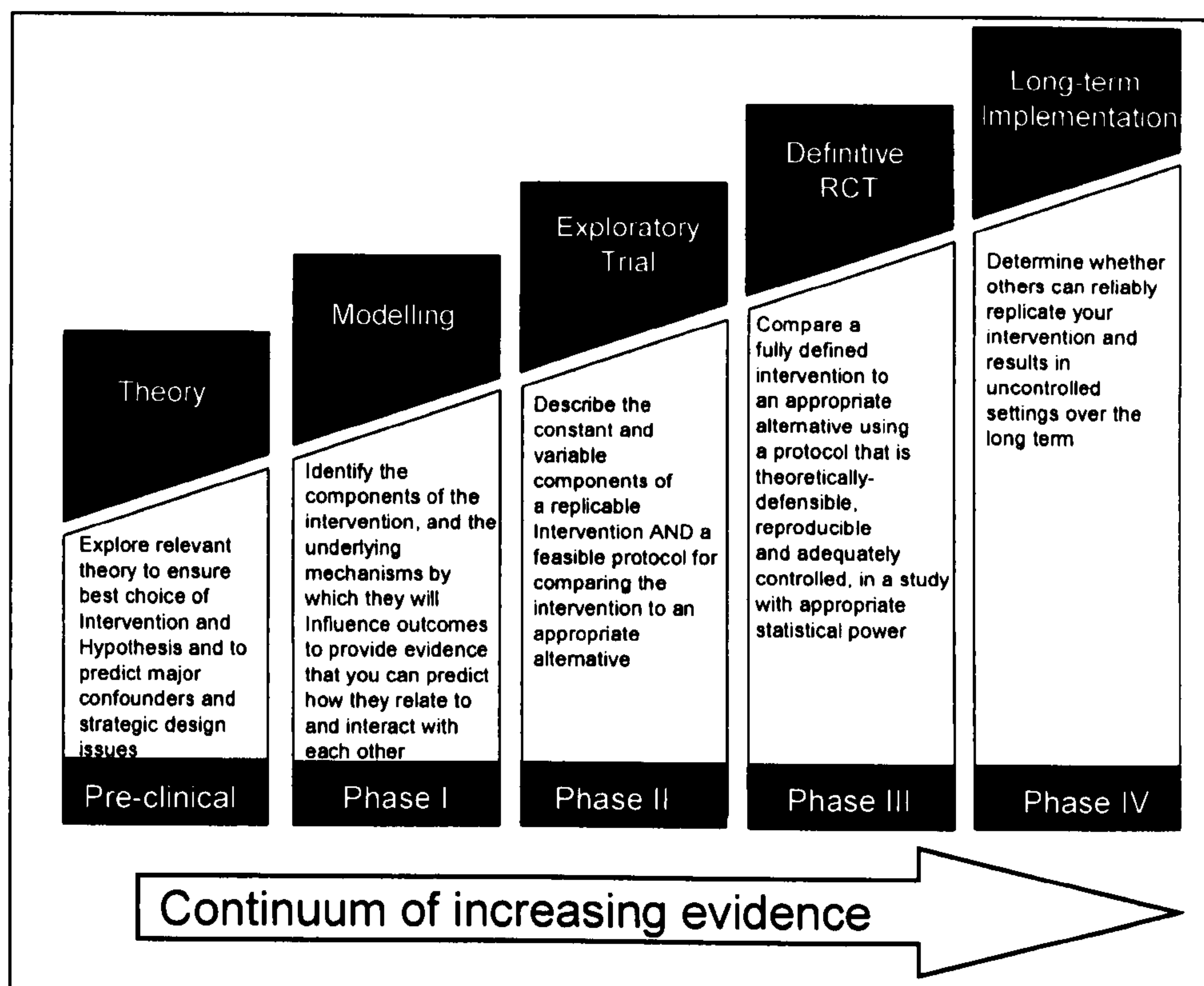
The pharmaceutical model, involves pre-clinical testing which refers to drug development before it is tested in humans (including compound development in the laboratory and animal testing), followed by four sequential phases of testing in humans:

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<sup>iv</sup> The Framework was published twice, firstly by the MRC as a framework for guiding development and evaluation of RCT studies of complex interventions and subsequently in the British Medical Journal as a framework for all complex intervention development in general.



**Figure 2. The MRC Framework for Developing RCTs of complex interventions.**



Source: MRC (2000).<sup>1</sup>

phase I trials investigate clinical pharmacology and toxicity; phase II involves the initial clinical investigation for treatment effect in humans; phase III trials involve the full-scale evaluation of treatment; and phase IV trials focus on post-marketing surveillance to determine uptake of the intervention.<sup>91,92</sup> In the MRC Framework the first ‘theoretical’ phase corresponds to a pre-clinical phase of pharmaceutical development, in this case where the theoretical assumptions are defined and the hypotheses are generated. The second phase, ‘modelling’, corresponds to Phase I in the pharmaceutical model and refers to the process of identifying the intervention components and the mechanisms by which they will influence outcomes. The MRC Framework includes a section on using qualitative research methods in the theoretical and modelling phases of intervention development, in which the authors recommend the use of qualitative methods to address unanswered questions particularly in relation to understanding the

‘active ingredients’ of the intervention.<sup>1</sup> The third phase, ‘exploratory trial’, corresponds to a phase II pharmaceutical trial in which the components are finalised and a protocol for the main trial is defined. The fourth phase ‘definitive RCT’ corresponds to a phase III pharmaceutical trial in which the intervention is compared to a suitable control to establish efficacy; and the final phase ‘long-term implementation’ corresponds to a phase IV pharmaceutical trial in which the definitive RCT results are investigated in an uncontrolled setting.

The MRC Framework can be seen as novel on two accounts. Firstly, it acknowledges the difficulty of applying RCT methods to complex interventions and secondly it stresses the importance of considering alternative approaches (qualitative methods) to investigating aspects of healthcare. In this context, The Framework can be seen as something of a ‘scientific revolution’.<sup>93</sup>

#### **2.4. Alternative frameworks for complex intervention development**

The MRC Framework has been criticised, in particular by those in the field of health promotion (where most of the interventions developed can be termed ‘complex’) for its focus on using RCT methods.<sup>9</sup> Many health promotion specialists argue that the choice of evaluation method should depend on the ‘ideology’ underpinning the intervention and the health question to be answered. It is the ideological underpinning of the interventions that dictates the types of methods appropriate. For example, Naidoo & Willis (2003) outline five different approaches to developing health promotion interventions.<sup>83</sup> These include (i) a medical approach, (ii) a behavioural approach, (iii) an educational approach, (iv) an empowerment approach and (v) a social change approach. The first three approaches (medical, behavioural and educational) are based on medical and psychological theories of health and focus on intervening at an



individual level, either treating the individual directly with medicinal or surgical intervention (medical model), or improving health outcomes through individual education and behaviour change. The last two (empowerment and social change models) focus on intervention at a social level either through empowering communities locally (community development) or through tackling inequalities on a broader national level (social change model). They argue that it is difficult to evaluate interventions incorporating certain types of approach using RCT methods (in particular, it is difficult to evaluate community empowerment or social change interventions).

The MRC Framework does not distinguish between interventions using different approaches, neither does it distinguish between interventions designed to influence short-term outcomes (such as improving knowledge) from those intended to achieve long-term outcomes (such as wealth distribution). The authors of The Framework make no reference to the health promotion literature, possibly suggesting that it is really only intended to be used to evaluate the first three types of health promotion intervention (medical, behavioural and educational models).

## **2.5. Formative, process and outcomes evaluation**

Within the health promotion and social science literature, alternative frameworks have been proposed for guiding evaluation of social or complex health interventions. Thorogood & Coombes suggest that different types of evaluation should be conducted to evaluate different aspects of programmes and conducted at different time points.<sup>94</sup> They identify three different types of evaluation necessary in programme development, formative, process and outcomes evaluation. *Formative evaluation* refers to research used to inform intervention development; *process evaluation* refers to research concerned with the implementation of the programme and its impact on processes

leading to the eventual outcomes; and *outcome evaluation* refers to research into the impact of the programme on the final endpoint that the programme aims to influence.<sup>94</sup> They describe a circular rather than linear relationship between the phases, meaning there is no definitive end to the research process. In other words, outcome evaluation should form the formative research required for the next programme and so on. Naidoo & Willis also outline three types of evaluation in health promotion: *process*, *impact* and *outcome* evaluation (p376).<sup>83</sup> They suggest that *process evaluation* (also called formative or illuminative evaluation) investigates participants' perceptions of the intervention and aims to identify factors, which act as facilitators or barriers to the intervention working. *Impact evaluation* refers to the immediate effects of the intervention on short-term outcomes (including patient knowledge, attitudes, health behaviours). *Outcome evaluation* is defined as assessment of the impact of the intervention on longer-term outcomes, such as health outcomes. They suggest that impact evaluation may be the one most accessible to evaluation using RCT methods.

There appears to be some variation across the literature over what exactly is meant by these different terms. Patton suggests that *formative evaluation* might include a *process evaluation* rather than the two being mutually exclusive 'phases', depending on its purpose<sup>95</sup>. In other words, if it is used at the end of a study to refine future versions of the intervention then it can be defined as formative evaluation; if it is used simply to explain outcomes then it is not 'formative', in this case it really depends on the end point of the study. Patton also uses the term *implementation evaluation*, which can be viewed as part of a process evaluation but focusing specifically on how the intervention is implemented. He quotes Walter Williams, who in 1976 said that

'the lack of concern for implementation is currently the crucial impediment to improving complex operating programs, policy analysis and experimentation in social policy areas' (in Patton, p27<sup>95</sup>).



Impact evaluation as defined by Naidoo & Willis appears to refer more to the method of evaluation than the purpose since, for some, the short term outcomes (impact evaluation) may be seen as part of the processes involved in the eventual success or failure of the intervention, even though they are not studied using statistical techniques.<sup>83</sup>

If the MRC Framework is visualised in the context of these health promotion definitions, the first three phases (theoretical, modelling and exploratory trial) can be seen as formative research and the main RCT can be seen as impact evaluation with the longer term implementation phase corresponding with 'outcome evaluation'. The MRC model also suggests a circular relationship between the different phases of intervention development. However, unlike the other models it does not include a process evaluation phase. Thus the MRC Framework can be seen as a simplified version of these health promotion models of evaluation, with the focus being on detailing the formative research phases to inform intervention development but including little guidance at the process, impact or outcome evaluation stage. Such simplifications do not automatically negate the status of The Framework as innovative since according to Kuhn, scientific revolutions occur not as a sudden shift in thinking but as part of a process of change, which reflects changes in broader social thinking.<sup>93</sup>

## **2.6. Action planning models**

As stated earlier, the MRC Framework is not the only evaluation model to have dissected intervention development processes into separate phases. Action planning models,<sup>96</sup> used within health promotion, organisational science and the military for strategic development, break down the planning process into distinct phases, some with similarities to those defined in the MRC Framework. Three of the best known models



include the model by Dignan & Carr,<sup>97</sup> the Precede-Proceed Model<sup>98</sup> and the Pabcar model.<sup>99</sup> Dignan & Carr suggest five phases to intervention development including: community analysis (analysis of community needs); targeted assessment (identification of key problems to address); programme plan development (identification of methods to address problems); implementation (consideration of implementation problems); evaluation (evaluation tools put in place). In the precede-proceed model, nine distinct phases are identified including six phases to diagnose needs and/or problems: social diagnosis; epidemiological diagnosis; behavioural and environmental diagnosis; educational and organisational diagnosis; administrative and policy diagnosis. The intervention is devised based on these diagnoses within the context of available resources and ability of the health promotion team to address them. The intervention is then implemented (phase seven) and three phases of evaluation used to understand impact (process evaluation; impact evaluation; outcome evaluation).<sup>98</sup> The Pabcar model recommends seven iterative phases: identify problem and target group; develop interventions and outcome based objectives; pilot research; assess intervention in terms of social impact; consideration of ethics, economic costs and efficacy; further pilot if necessary; implement intervention; monitor problem, evaluate intervention and change if required.<sup>99</sup>

Each of these models is slightly different in the number and focus of the phases included but they have in common, three distinct differences when compared to the MRC Framework. Firstly, each model suggests the type of theoretical investigation or analysis which should be conducted, including a form of social or community diagnosis of the problem to be addressed; secondly, each model incorporates implementation and process evaluations as distinct phases in addition to the impact or outcome evaluation; thirdly none of the models identifies a specific method that should be used in outcomes

evaluation and none of them specifically reference the use of RCT methods. In fact the authors of the Pabcar model suggest that RCT methods may be inappropriate for outcome evaluation since successful implementation requires ongoing monitoring, evaluation and change, something not permitted within the context of a RCT.<sup>99</sup>

## **2.7. Using qualitative methods in intervention development and evaluation**

Although often considered to be of low status in the evidence-based medicine hierarchy for generating research evidence,<sup>82,100</sup> health promotion specialists and indeed clinicians and social scientists are increasingly arguing for the use of ‘qualitative methods’, if not instead of, then alongside or embedded within RCT methods for investigating interventions.<sup>73,81,82,100-102</sup> The phrase ‘qualitative method’ is often used to refer to specific data collection techniques such as in-depth interviewing, focus groups studies or participant observation (as in the MRC Framework). In this thesis, I use the term to refer to data collection tools within a specific paradigm, that is techniques for understanding phenomena when adopting a ‘non-positivist’ approach. In a non-positivist tradition (for example a constructivist approach), the researcher does not subscribe to traditional scientific principles such as attempting to expose or report scientific ‘truth’ or testing specific hypotheses. Rather, the aim is to construct ideas, ask questions, generate hypotheses or theorise about how and why particular phenomena occur in the way that they do. Such approaches are traditionally rooted in the disciplines of anthropology, sociology and social psychology<sup>103</sup> (although these disciplines do not exclusively subscribe to non-positivist approaches).

Use of qualitative methods within public health and HSR is becoming increasingly common, although not without criticism from theorists. It is argued that atheoretical attempts by HSR researchers to apply the tools for the trade (interviews for example)



have led to research that contributes little to our understanding of health, or to our understanding of cultural, psychological or social phenomena.<sup>103,104</sup>

Whether appropriate or not, qualitative methods have been used for a number of different purposes in relation to intervention development and evaluation including: to improve communication of trial process to patients to improve trial recruitment;<sup>105,106</sup> to understand users' views or experience prior to intervention development;<sup>107-109</sup> to develop trial methods including outcome measures;<sup>110,111</sup> to understand intervention implementation;<sup>112-116</sup> as a data monitoring procedure to ensure patient safety;<sup>117,118</sup> and to investigate the impact of the intervention on trial participants' experiences.<sup>119,120</sup> Two studies have even incorporated qualitative methods into intervention studies as a result of the MRC Framework.<sup>117,121</sup> However, there has been little critique of this approach and while some have suggested that the use of formative or process evaluation may be problematic,<sup>87,122,123</sup> it is more generally accepted that process evaluation poses no methodological problems when used alongside more traditional RCT methods.<sup>73,86,95,100,115,117</sup>

In this thesis the challenges of using qualitative methods in intervention and evaluation, including embedding process evaluation within a RCT will be investigated in the context of Stop Stroke intervention and trial evaluation.

## **2.8. Summary**

Finding the best way to develop and evaluate complex interventions has become an increasingly important question in public health and clinical practice over the past decade. In clinical research the RCT is held to be the 'gold standard' method of evaluation for producing objective research evidence. But the application of RCT methods in complex intervention evaluation can be problematic. The MRC Framework

was designed to guide those contemplating complex intervention development. It has not yet been demonstrated whether the framework will make a difference. However, similar health promotion models for intervention development suggest that in order to understand the impact and outcomes of complex intervention studies, research should include process and implementation evaluations, something omitted from the MRC Framework. Further research is needed to investigate the application of The Framework in practice. In this thesis I investigate The Framework as a measure of quality in intervention development and in subsequent chapters as a practical tool for guiding development and evaluation of the Stop Stroke intervention.



## **Chapter 3. Review of complex intervention development in stroke care**

### **3.1 Introduction**

In this chapter I focus specifically on the development of complex interventions in stroke care, presenting findings from a systematic review of empirical studies of complex interventions in stroke care. Although the focus of the Stop Stroke study is on secondary prevention, due to the paucity of intervention studies in this area the review has been broadened to include all complex interventions studies in prevention and stroke management. I have previously reviewed the efficacy of complex interventions in stroke care<sup>124</sup>. In this review I aim to investigate the theoretical grounding and research methods used to develop and evaluate interventions and explore the relationship between intervention and study design and the eventual success or failure of the intervention. The following questions will be addressed: (i) what complex interventions have been developed in the context of stroke prevention and management; (ii) what theories and methods have been used to develop and evaluate these interventions; and (iii) what influence does theoretical and methodological quality have on study outcomes?

### **3.2. Methods**

The review included published evaluations of complex interventions in stroke prevention and management. Since there is little clarity over the definition of a 'complex intervention' (Chapter 2), for the purposes of this review I defined complex interventions as educational or psychosocial interventions aimed at changing knowledge, beliefs or behaviours. Specific rehabilitation or therapy interventions and those targeted at service organisation were excluded. These were: diagnostic tools; non-

pharmacological therapies (including complementary medicine, physiotherapy, occupational therapy, speech and language therapy, cognitive-behavioural therapy); stroke units; early discharge interventions; integrated stroke care-pathways.

The review was not restricted by language or study design but interventions evaluated only in preliminary analyses or pilot studies were excluded.

### *3.2.1. Search strategy*

I used multiple search strategies to identify articles for inclusion: electronic online database searches; hand searching of individual journals; and a 'grey literature' search. Five online databases were searched: MEDLINE 1966-2005; EMBASE 1980-2005; PsychInfo 1967-2005; Science Citation Index (SCI) and Social Science Citation Index (SSCI) 1900-2005. Recent journals (2000-2005) were hand searched to crosscheck for articles not identified by the electronic search (Stroke, Cerebrovascular Diseases, Lancet, New England Journal of Medicine, JAMA, BMJ, Health Education Research, Health Psychology, British Journal of Health Psychology, Social Science and Medicine, Patient Education and Counseling, Journal of Advanced Nursing, Health Promotion International). Existing reviews, UK health education and health policy documents were searched, as were the reference lists of included articles. Both a MeSH subject heading search and a key word search were conducted (last searched November 2005). The choice of search terms was guided by the MRC Framework<sup>1</sup> and included multiple key words and phrases<sup>v</sup>. Articles describing the theoretical or methodological development of included studies were retrieved in addition to those documenting the evaluation itself.

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<sup>v</sup> For the subject-heading search the following strategy was used:

- 1) Subject headings 'stroke', 'cerebrovascular accident', 'cerebrovascular disorders' were combined using the Boolean operator 'OR'.
- 2) Subject headings 'prevention', 'primary prevention', 'secondary prevention', 'recurrence', 'risk management', 'disease management', 'patient care', 'health care delivery', 'rehabilitation', 'social



I conducted the search myself and rated studies for inclusion. Where it was unclear whether or not a study should be included, relevant articles were retrieved and discussed with one of my supervisors (CM) until consensus was achieved. In one case where the article could not be retrieved, the authors were contacted to request the full article. Decisions on four studies published in languages other than English were made based on translations of the abstract. The key article of the one study judged to be relevant, was retrieved in Chinese and translated in full.

I categorised interventions by study aim and target group. Data were extracted into pre-designed tables to ensure standardisation across studies.

### 3.2.2. *Analysis*

Since the review focused on the influence of theoretical and methodological development rather than on intervention efficacy, a meta-analysis was not conducted.

A number of criteria exist for evaluating study quality but most are not relevant in the context of this review (for example 'blinding' is a less relevant criterion to assess most complex interventions where it is impossible to conceal from intervention recipients or

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support', 'counselling', 'education', 'health promotion', 'decision making', 'primary healthcare', 'health care psychology', 'medical psychology', 'clinical psychology', 'compliance', 'patient compliance', 'guideline adherence', 'access to information', 'access to healthcare', 'behaviour', 'screening', 'health screening', 'knowledge', 'health knowledge' were combined using the Boolean operator 'OR'.

3) subject headings 'intervention studies', 'evaluation studies', 'randomised controlled trials' were combined with the Boolean operator 'OR'.

The results of searches 1), 2) and 3) were combined with the Boolean operator 'AND'.

For the key word search the following strategy was used:

1) The key words: 'stroke', 'cerebrovascular' were combined with the Boolean operator 'OR'

2) The key words: 'intervention', 'trial' were combined with the Boolean operator 'OR'

3) The key words: 'prevention', 'management', 'behaviour', 'behavior', 'recurrence', 'recovery', 'rehabilitation', 'knowledge', 'compliance', 'adherence', 'concordance', 'access', 'education', 'counselling', 'counseling', 'complex', 'social', 'community', 'decision support', 'psychological', 'psychosocial', 'quasi experiment\*', 'quasi randomised', 'pre test post test', 'time series' were combined with the Boolean operator 'OR'.

The results of the searches 1) 2) and 3) were combined with the Boolean operator 'AND'.

The results of the MeSH subject heading and key word searches were then combined with the Boolean operator 'OR'.

providers whether or not they have received the intervention).<sup>125</sup> Instead, I defined quality criteria using the MRC Framework recommendations for study development. Studies were first classified according to the reported development process and whether the intervention was theoretically grounded (Table 1).

**Table 1. Criteria to assess theoretical quality.**

Quality assessment	Theoretical justification
A) well grounded	The intervention itself was informed by some form of literature review and in addition by either an established theoretical framework or empirical investigation conducted by the authors.
B) moderately grounded	A detailed analysis of at least one of the following was reported: an established theoretical framework; evidence from a published systematic review supporting the intervention; empirical investigation conducted by the authors; or review of empirical studies conducted by the authors supporting the intervention.
C) minimally grounded	A brief overview of literature was reported in support of the intervention or a detailed review of the study area but not specifically in support of the intervention.
D) no theoretical grounding	Interventions did not report any research/cite any literature to support the use of the intervention.

Secondly, they were classified according to the chosen evaluation methods: RCT versus other designs; outcome measures (primary and secondary outcomes and use of standardised assessment measures) and consideration of statistical power. I considered it unlikely that studies would report explicit ‘phases’ of intervention development since the MRC Framework is not routinely used for this purpose. Studies might also pre-date The Framework.

The impact of interventions on outcomes (study ‘success’) was defined using three criteria: interventions demonstrating a significant beneficial impact on all primary



outcomes were defined as ‘successful’; those having a beneficial impact on at least one but not all primary outcomes were defined as ‘partially successful’; those which either failed to demonstrate an impact on any primary outcomes, or demonstrated a detrimental impact were defined as ‘failed’. Simple frequencies were used to describe study characteristics and  $\chi^2$  tests used to explore associations between aspects of study design and outcomes.

### 3.3. Results

Over 12000 references were identified and 733 retrieved yielding 95 articles covering 67 complex intervention studies. Six hundred and thirty-eight articles were excluded: 293 were not evaluation studies; 217 referred to specific interventions excluded from the review; 98 were not stroke specific; 21 reported pilot or preliminary findings only; nine were not ‘complex’. Of the included studies, 40 were evaluated using RCTs and 27 using quasi-experimental, observational and/or qualitative designs. Interventions covered four broad themes: those aimed at changing professional behaviours in preventing and managing stroke (Table 2); those targeted at people from the general population and patients to improve primary and secondary prevention (Table 3); and those targeted at stroke patients and carers to improve recovery and adjustment after stroke (Table 4). Professional interventions included locally disseminated guidelines,<sup>126-129</sup> stroke orders or protocols,<sup>130-135</sup> a tool to aid clinical decision making<sup>136</sup>; and training and/or academic detailing.<sup>107,137-145</sup> Primary prevention interventions included information and feedback,<sup>158,163</sup> media campaigns,<sup>149,160</sup> peer support and education,<sup>154</sup> patient decision- aids,<sup>150,161,162</sup> and multi-factorial educational, screening and monitoring programmes.<sup>146,152,153,155,156,159,165,166</sup> Secondary prevention interventions included a shared medical record,<sup>148</sup> an intervention incorporating a shared record plus

Table 2. Summary of complex intervention studies targeted at health professionals.

Study, date & country	Participants	Components, ‘dose’ & duration	Theoretical rating	Study Design*	No. primary outcome measures	Success in primary outcomes**
Booth 2005 <sup>137</sup> UK	37 patients; 6 nursing staff.	Seven hours of education delivered by a senior therapist, covering positioning, therapeutic handling of patients and facilitation of morning activities. Teaching methods included: 1. formal lectures; 2. simulated patient demonstrations; 3. video demonstrations; 4. experiential learning.	A	QE	2	P
Bray 2005 <sup>138</sup> Australia	61 paramedics in emergency services units; 18 intervention; 43 control.	1. A one-hour education session covering: stroke aetiology, symptoms, risk factors, assessment, documentation of onset, diagnosis and management. 2. Instruction in the use of Melbourne Ambulance Stroke Screen assessment tool (MASS).	B	QE	2	P
CASPR 2005 <sup>130</sup> USA	423 patients with a diagnosis of ischaemic stroke at 6 hospitals.	Stroke ‘orders’ provided on hospital discharge containing templates and checklists of best practice recommendations for nurses to complete.	A	BA	6	P
Eo 2002 <sup>139</sup> South Korea	164 paramedics.	Training in stroke knowledge from three emergency specialists covering stroke definition, signs and symptoms, pre-hospital neurological examination and emergency care. ‘Dose’ not specified.	D	BA	7	P

Study, date & country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design*	No. primary outcome measures	Success in primary outcomes**
<b>Forster</b> 1999 <sup>107,140</sup> <b>UK</b>	32/40 nurses	1. Two theory-based lectures from a physiotherapist. 2. A two-hour interactive practical session. Programme delivery designed to fit around shifts, to improve access to training.	B	BA + Qual	2	S
<b>Heinneman</b> 2003 <sup>141</sup> <b>USA</b>	131/352 doctors; 134/244 other health professionals.	1. A one-hour lecture covering the clinical practice guidelines. 2. A packet of information on post stroke rehabilitation.	B	BA	1	P
<b>Jackson</b> 2004 <sup>126</sup> <b>Australia</b>	162/272 general practitioners (GP).	1. All practitioners receive copies of guidelines on prescribing highlighting under-use of antithrombotics. 2. One educational visit from a pharmacist. 3. Distribution of computer mouse pads embossed with AF guidelines in a flowchart form and RHH anticoagulation guidelines.	C	QE	3	P
<b>Monaghan</b> 2005 <sup>131</sup> <b>UK</b>	75 patients admitted to a stroke rehabilitation ward.	<i>Intervention one</i> 1. A form for recording problems in achieving patients' rehabilitation goals to encourage patient participation in goal setting. <i>Intervention two</i> 2. Discussion of patients' treatment plans at the foot of the patient's bed so patients could become involved in planning.	C	QE-TS	5	P



Study, date & country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design*	No. primary outcome measures	Success in primary outcomes**
<b>Nir 2004</b> <sup>132</sup> <b>Israel</b>	155 stroke survivors aged 57-93: 82 intervention; 73 control.	A 19-day structured written nursing rehabilitation program consisting of a guidebook and feedback form with topics addressing common stroke problems, tailored to the individual patient and caregiver (focusing on affective, cognitive and instrumental domains).	D	RCT	7	P
<b>Pennington 2005</b> <sup>142</sup> <b>UK</b>	717 stroke patients; 36 speech and language therapists and their teams.	Two teaching strategies to improve adherence to clinical guidelines on speech and language therapy: 1. 2.5 days training over seven weeks in clinical governance, evidence based healthcare, critical appraisal, research methods and evidence-based guidelines (short talks, group discussion, problem-based learning and self directed study); 2. Five fortnightly training days (as above), plus 2.5 additional training days on how to implement practice change.	B	RCT	1	F
<b>PRISM 2003</b> <sup>136</sup> <b>UK</b>	1952 acute ischaemic stroke patients attending 16 hospital centres. Clinicians (N) unknown.	Single intervention using a computer based decision support system (CDSS) for prescribing six potential antithrombotic therapies. Graphical presentation of risk estimates faxed to staff as soon as possible after patients present at hospital/clinic. Output is placed in medical record for use in future prescribing decision.	B	RCT	1	F



Study, date & country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design*	No. primary outcome measures	Success in primary outcomes**
<b>PROTECT</b> 2004 <sup>133-135</sup> USA	130/144 consecutive patients acute stroke/TIA patients admitted to a university hospital stroke service.	A toolkit to improve initiation and maintenance of eight secondary prevention programme goals in hospital. The toolkit includes: 1. pocket cards with programme goals; 2. patient information sheets; 3. pre-printed admission orders; 4. educational sheet to document implementation; 5. telephone call at two to four weeks post discharge.	C	BA	8	P
<b>SAFIRE</b> 2004 <sup>143</sup> Australia	715 patients, 121 physicians, 452 residential care staff.	1. Two 30-minute outreach detailing visits by a pharmacist in the physician's surgery focusing on evidence-based guidelines on falls prevention. 2. Audit data on fall rates, prescribing patterns and risk reduction practices.	B	RCT	1	F
<b>Sheikh</b> 2004 <sup>127</sup> USA	Medicare beneficiaries aged 65+ years in 14 states.	1. Development of indicators, outcome measures, conferences, meetings, newsletters. 2. State-wide data feedback on indications, contraindications for treatment. 3. Local data analysis to evaluate quality.	D	QE-MC	2	P
<b>Silagy</b> 2002 <sup>128</sup> Australia	243 GPs.	Single dissemination of locally adapted guidelines developed using: i. formal assessment of national scientific evidence by a multi-disciplinary team; ii. panel meetings; iii. open forum sessions.	D	RCT	2	S

Study, date & country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design*	No. primary outcome measures	Success in primary outcomes**
<b>Williams 2003<sup>129</sup></b> <b>UK</b>	Professionals admitting a single teaching hospital.	A multidisciplinary online clinical information service (MOCIS) providing best practice evidence including stroke care.	C	QE-TS	1	P
<b>Zhang 2003<sup>144,145</sup></b> <b>China</b>	8 Community nurses and 60 stroke patients discharged to the community.	A self-care training programme for nurses with standardised, individualised and family focused components tailored to the patient's rehabilitation needs.	B	RCT	4	S

\* Design abbreviations: Randomised Controlled Trial (RCT); Quasi-experimental study (QE); time series controlled design (QE-TS); before and after study (BA); qualitative evaluation (Qual).

\*\* Outcome success: successful in all primary outcomes (S); partially successful i.e. success in at least one but not all primary outcomes (P); failure in all primary outcomes (F).

Table 3. Studies targeting primary and secondary stroke prevention.

Study, date, country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design	No. primary outcome measures	Success in primary outcomes**
Agewall 1994 <sup>146</sup> Sweden	508 male treated hypertensives aged 50-72 with high cholesterol, diabetes or smoking.	<ol style="list-style-type: none"><li>1. Group information on risk factors.</li><li>2. Ongoing monitoring and prescription of pharmacological therapy.</li><li>3. Smoking cessation programme: physician visits and five one-hour weekly meetings, prescription of nicotine gum.</li></ol>	C	RCT	8	P
Allen 2004 <sup>147</sup> USA	96 stroke/TIA patients.	<ol style="list-style-type: none"><li>1. In-home bio-psychosocial assessment (one-month post discharge).</li><li>2. Review by an interdisciplinary stroke team within seven days.</li><li>3. Delivery of personalised self- management plans on risk factor and depression management to patients and primary care professionals.</li></ol>	A	RCT	1	S
Banet 1997 <sup>148</sup> USA	52 patients discharged after first stroke.	<p>One-off intervention delivered in hospital:</p> <ol style="list-style-type: none"><li>i. Shared medical record;</li><li>ii. Inpatient teaching;</li><li>iii. American Stroke Association leaflets.</li></ol>	C	RCT	3	F

Study, date, country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design	No. primary outcome measures	Success in primary outcomes**
<b>Becker 2001<sup>149</sup></b> <b>USA</b>	547/6087 English speaking respondents to a telephone survey.	A four-month social marketing intervention educating people about stroke, the need to call 911 and the need to attend risk factor screenings. Delivered through: <ul style="list-style-type: none"> <li>i. public service announcements;</li> <li>ii. television;</li> <li>iii. advertising in newspaper;</li> <li>iv. public stroke screenings;</li> <li>v. distribution of 'Brain attack' fliers advertising the screenings.</li> </ul>	C	BA	4	P
<b>DAAFI 2005<sup>150</sup></b> <b>Canada</b>	Adult community NVAf patients, with no indications/contraindications for Warfarin.	A decision aid booklet for patients outlining the risks and benefits of anticoagulant therapy.	B	RCT	1	S
<b>Ellis 2005<sup>151</sup></b> <b>UK</b>	205 patients diagnosed with stroke, TIA or amaurosis fugax three months previously, plus one or more risk factors & no cognitive impairments.	<ul style="list-style-type: none"> <li>1. Monthly risk factor monitoring reviews (over a three month period) from a specialist stroke nurse delivered in outpatients departments.</li> <li>2. Individualised secondary prevention advice tailored to the patient's functional ability.</li> <li>3. Patient-held record detailing risk factor control targets, updated at each visit.</li> </ul>	B	RCT	6	F



Study, date, country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design	No. primary outcome measures	Success in primary outcomes**
<b>Eriksson 1997<sup>152</sup></b> <b>Sweden</b>	295 patients with hypertension diabetes or post MI attending county health institutions.	38 hours of stroke prevention training plus a four-day refresher course one year later: i. Patient education and discussion on exercise, relaxation, physiology, food preparation, addiction and healthy living; ii. Formal lectures on hypertension, diabetes, MI and nutrition; iii. Individual guidance from a dietician, a physiotherapist, a fitness assistant, a nurse and a physician.	B	BA	5	P
<b>Fang 1999<sup>153</sup></b> <b>China</b>	General population: 18,786 intervention, 18,876 control.	1. Fortnightly risk factor monitoring visits 1987-1990 for patients with hypertension or diabetes. 2. Weekly visits from intervention doctors providing individualised treatment. 3. Health education program to all the residents.	C	QE	1	S
<b>Glanz 1986<sup>154</sup></b> <b>USA</b>	67 (intervention) and 43 (control) participants at two senior citizen centres.	1. A single education session plus two booster sessions to train peer facilitators (PF) in stroke, TIA, risk factor control stress management, medication, communication skills and health service use. 2. Peer support and education delivered by PFs to elderly care residents ('dose' not reported).	B	QE	9	S
<b>HDFP 1984<sup>155</sup></b> <b>USA</b>	10,940 participants with a diastolic blood pressure $\geq$ 90mmHg.	Stepped care therapy at clinics involving: i. blood pressure assessment and follow-up; ii. goal setting and prescription of pharmacological therapy to reduce diastolic BP<90mmHg; iii. Number and duration of visits not reported.	D	RCT	2	S

Study, date, country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design	No. primary outcome measures	Success in primary outcomes**
Iso 1998 <sup>156</sup> Japan	General population: 3219 (full), 1468 (minimal).	<i>Minimal intervention (control)</i>	D	QE	5	S
		1. Blood pressure screening. 2. Follow-up every two years. <i>Full intervention (cases)</i> 3. Blood pressure screening. 4. Referral to clinics for high-risk individuals. 5. Health education at screening sites. 6. Adult classes and nurse home visits. 7. Training about healthy diet. 8. Community-wide media disseminated education to encourage participation in screening.				
Jiang 2004 <sup>157</sup> China	1558 people with first stroke: 736 intervention; 820 control.	1. Hypertension screening over a three-year period. 2. Monitoring and counselling. 3. Community-based health education.	B	QE	2	S
Kreuter 1995 <sup>158</sup> USA	1317 patients in primary care.	<i>Standard intervention</i> 1. Computer generated risk feedback with illustrations/graphical representation explaining 10-year mortality risk and risk reduction strategies. <i>Enhanced intervention</i> 2. Risk feedback. 3. Behaviour change feedback plus individually tailored messages targeting patients' perceptions. Both single dose interventions.	B	RCT	1	P

Study, date, country	Participants	Components, ‘dose’ & duration	Theoretical rating	Study Design	No. primary outcome measures	Success in primary outcomes**
Lin 2004 <sup>159</sup> Taiwan	4977/5965 people in the general population aged 40+ years.	<ol style="list-style-type: none"> <li>1. Hypertension screening plus follow-up delivered by 143 volunteer villagers at one year and 3.5 years.</li> <li>2. Health education.</li> <li>3. Village based hypertension campaigns.</li> <li>4. Yearly weight control and smoking cessation classes.</li> <li>5. Yearly television broadcasts .</li> </ol>	A	BA	4	S
Lindsey 2000 <sup>160</sup> USA	3116 people living in a north western community.	A multi-factorial campaign: <ol style="list-style-type: none"> <li>i. one-hour TV broadcast advertising a stroke screening schedule (two months prior to screening.</li> <li>ii. local newspaper articles on stroke plus the screening schedule.</li> </ol>	D	BA + control cohort	1	S
Man-Son-Hing 1999 <sup>161,162</sup> USA/Canada	287 patients with atrial fibrillation from an aspirin cohort study.	<ol style="list-style-type: none"> <li>1. Single delivery of a patient decision booklet, plus a personal worksheet on consequences of stroke and Warfarin monitoring. Estimates of stroke risk for different therapies provided.</li> <li>2. Physicians receive a manual on the decision aid.</li> </ol>	B	RCT	5	S



Study, date, country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design	No. primary outcome measures	Success in primary outcomes**
<b>Mazor 2002<sup>163</sup></b> USA	A convenience sample of 177 volunteers, aged 18+ yrs, able to read and write English and without specialist stroke knowledge.	<p><i>Single 'dose' information packet interventions</i></p> <ol style="list-style-type: none"> <li>1. short factual information on stroke.</li> <li>2. facts + pathophysiology.</li> <li>3. facts + explanations of causal links.</li> <li>4. pathophysiology and explanation.</li> <li>5. fictitious account of a person having a stroke.</li> </ol> <p><i>Control intervention</i></p> <ol style="list-style-type: none"> <li>1. information on cholesterol cancer.</li> </ol>	B	RCT	1	P
<b>Rimmer 2000<sup>164</sup></b> USA	35 stroke survivors >six months post stroke.	<p>3 educational sessions over 12 weeks:</p> <ol style="list-style-type: none"> <li>1. fitness class;</li> <li>2. hands-on meal preparation;</li> <li>3. psychosocial intervention incorporating 'Stages of Change' model.</li> </ol>	B	QE	8	P
<b>Stern 1998<sup>165</sup></b> USA	657 adults living in the community or senior independent living settings.	<p><i>Intervention one</i></p> <ol style="list-style-type: none"> <li>1. A professionally produced slide/audio educational programme on stroke types and the warning signs.</li> </ol> <p><i>Intervention two</i></p> <ol style="list-style-type: none"> <li>2. Slide/audio programme.</li> <li>3. Review of content with a facilitator.</li> </ol>	B	BA	1	S

Study, date, country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design	No. primary outcome measures	Success in primary outcomes**
Willoughby 2001 <sup>166</sup> USA	85/107 volunteers attending a stroke screening programme.	<ol style="list-style-type: none"> <li>1. Single screening for stroke risk factors.</li> <li>2. Nurse counselling on ways to reduce stroke risk.</li> <li>3. Dietician and pharmacist advice.</li> <li>4. National Stroke Association stroke reduction plan.</li> </ol>	C	BA	3	S

\* Design abbreviations: Randomised Controlled Trial (RCT); Quasi-experimental study (QE); time series controlled design (QE-TS); before and after study (BA); qualitative evaluation (Qual).

\*\* Outcome success: successful in all primary outcomes (S); partially successful i.e. success in at least one but not all primary outcomes (P); failure in all primary outcomes (F).

Table 4. Summary of studies targeting patients and carers to improve adjustment and recovery after stroke.

Study, date, country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design	No. primary outcome measures	Success in primary outcomes**
Ayana 2001 <sup>167</sup> UK	252 stroke inpatients.	A patient-held record used over a six-month period for therapists to record details of each of the main needs/problems they dealt with. Patients could also record their own comments.	B	QE-TS	3	P
Boter 2004 <sup>168,169</sup> Netherlands	536/691 hospitalised first stroke patients. Strict eligibility criteria.	<ol style="list-style-type: none"><li>1. Three telephone contacts by a specialist stroke nurse.</li><li>2. One home visit – duration tailored to the individual family.</li><li>3. Nurses provided information, reassurance and problem solving advice using a standardised checklist of topics.</li></ol>	C	RCT	1	F
Clark 2003 <sup>170</sup> Australia	62 community stroke patients and spouses: 32 intervention, 30 control.	<ol style="list-style-type: none"><li>1. Stroke information package covering stroke consequences, secondary prevention, coping and social support services.</li><li>2. Three one-hour visits from a social worker at three time points: three-weeks, two-months and five-months post discharge.</li></ol>	A	RCT	3	S
Dennis 1997 <sup>171</sup> UK	417 stroke patients.	Individualised stroke Family Support Officer visits (ranging between zero and 17 contacts) aiming to: <ol style="list-style-type: none"><li>i. co-ordinate between health care services, social services and voluntary agencies;</li><li>ii. provide counselling.</li></ol>	D	RCT	12	F



Study, date, country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design	No. primary outcome measures	Success in primary outcomes**
Duhamel 2004 <sup>120</sup> Canada	Two MI patients and their families (spouse or caregiver); Two stroke patients and their families.	Family systems nursing intervention delivered at two week intervals: 1. five 30-minute pre-clinical sessions with nursing staff only; 2. five 60-minute clinical sessions in which family members participated in finding solutions to facilitate rehabilitation.	A	Qual	The authors used a constructivist approach and did test specific hypotheses.	Not applicable.
Evans 1984 <sup>172</sup> USA	43 stroke patients and carers/family members.	1. Single stroke class including formal teaching and group discussion on: stroke physiology, cognitive and perceptual changes, home visits, home modifications and architectural barriers. 2. Folder with resource materials.	B	BA	2	S
Evans 1998 <sup>173</sup> USA	188 stroke carers.	<i>Intervention one:</i> two weekly education sessions 1. OT-led classes during the third week of hospitalisation, lecture plus a video on consequences of stroke. 2. Social worker-led class within three days of first OT-led class, on treatments. <i>Intervention two:</i> counselling delivered over 12+ weeks 1. Education as above. 2. Seven one-hour sessions with social workers trained in cognitive behavioural therapy to develop coping strategies.	B	RCT	4	S

Study, date, country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design	No. primary outcome measures	Success in primary outcomes**
<b>FIRST</b> <b>2004</b> <sup>174,175</sup> <b>USA</b>	291/1683 stroke patients aged 45+ admitted to four acute-care hospitals and four rehabilitation hospitals.	15 weekly/fortnightly family meetings lasting approx. 90 minutes during the first six months post stroke provided by a clinical psychologist or social worker and including: i. education; ii. social support network cohesion; iii. training in problem solving.	A	RCT	1	F
<b>Forster</b> <b>1996</b> <sup>112,119,176</sup> <b>UK</b>	240 patients with stroke.	1. Approx. eight visits from a nurse support worker over six months providing advice on goal setting, problem-solving and specific issues. 2. Information packs containing detailed information on benefits.	A	RCT + Qual	1	F
<b>Frank 2000</b> <sup>177</sup> <b>UK</b>	39 community. patients less than two years post stroke.	1. Workbook intervention designed to increase perceptions of control. 2. Two weekly telephone follow-ups to give patients the opportunity to ask questions.	C	RCT	3	F
<b>Friedland</b> <b>1992</b> <sup>178,179</sup> <b>Canada</b>	88 community stroke patients recently discharged from an OT agency.	Eight to 12 weekly social support sessions from occupational therapists focusing on mapping individual social support systems, identifying deficiencies and goal setting.	C	RCT	2	F

Study, date, country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design	No. primary outcome measures	Success in primary outcomes**
<b>Geddes1989<sup>180</sup> UK</b>	19 patients lacking social support admitted to a stroke rehabilitation unit; 61 controls.	Social support intervention involving the use of 'substitute families' for patients discharged from hospital after stroke. It is unclear how long the intervention lasted.	D	QE	3	S
<b>Grant 2001<sup>181,182</sup> USA</b>	74 hospitalised ischaemic stroke survivors and their primary carers.	<ol style="list-style-type: none"> <li>Four weekly sessions from a nurse at one to four weeks post discharge to provide training in problem solving for family carers.</li> <li>Fortnightly telephone follow-up by nurses at six to twelve weeks post discharge.</li> </ol>	A	RCT	6	P
<b>Harari 2004<sup>183</sup> UK</b>	146/1715 hospital stroke patients. Patients included if they had >1 criteria used to diagnose bowel problems, no severe deficits. Patients without social networks or unlikely to finish the trial excluded.	<ol style="list-style-type: none"> <li>One-off assessment using an evidence-based protocol by a trained nurse.</li> <li>Targeted patient and carer education; provision of a booklet.</li> <li>Diagnostic summary and treatment recommendations sent to the patient's GP and ward physician.</li> </ol>	B	RCT	1	S



Study, date, country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design	No. primary outcome measures	Success in primary outcomes**
Hartke 2003 <sup>184</sup> USA	88/500 spouses of stroke survivors acting as primary carers for ≥ 1 month.	Eight 1-hour telephone support sessions for stroke carers facilitated by a psychologist, social worker or nurse covering stroke facts, communication, problem solving, stress and goal setting.	A	RCT	5	F
Johnson & Pearson 2000 <sup>110</sup> USA	41/430 community stroke survivors responding to a mailing.	Eight 2-hour structured classes delivered over a four-week period covering stroke facts, disability, emotional aspects of stroke, self-esteem and ways of encouraging a positive active lifestyle.	A	QE-MC	3	P
Kalra 2004 <sup>185</sup> UK	268/300 patients randomised, 134 intervention, 134 control.	1. Three to five (30-45 min) tailored hands-on caregiver training sessions on common stroke related problems prior to discharge from hospital. 2. One follow-up home training session post discharge. Training focused on instruction about common stroke related problems.	B	RCT	7	P
Lai 2004 <sup>111</sup> China	21 stroke patients living at home.	Weekly 1.5hour video conferencing rehabilitation sessions delivered over eight weeks and provided by a physiotherapist: i. educational talks on stroke physiology, symptoms, clinical and social services, risk factor control, psychosocial impact, and safety in the home; ii. 30 minute exercise sessions focusing on strength and balance; iii. social support.	B	BA + Qual	5	P

Study, date, country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design	No. primary outcome measures	Success in primary outcomes**
<b>Larson 2005<sup>186</sup></b> Sweden	91/253 eligible spouses of stroke patients completing one-year follow-up.	Six 20-30 minute education and support sessions (lectures plus group discussions) focusing on stroke facts and delivered over a six-month period in hospital by specialist stroke nurses.	C	RCT	4	F
<b>Lincoln 2003<sup>187</sup></b> UK	250 stroke patients admitted to hospital and their informal carers: 126 intervention; 124 control.	1. Contact from a Family Support Officer 2 weeks after recruitment, to provide liaison with the rehabilitation team whilst in hospital. 2. Post discharge follow-up at home for up to 9 months to discuss problems, offer information and support and direct families to appropriate services.	B	RCT	6	P
<b>Lomer 1987<sup>188</sup></b> UK	91 stroke patients admitted to medical and elderly care wards at two teaching hospitals.	Single distribution of an information leaflet delivered 2 weeks after admission to hospital with simple hand drawn illustrations focusing on stroke facts, available services, financial benefits and staff contact details.	B	RCT	4	P
<b>Lorenc 1992<sup>189</sup></b> UK	30 patients hospitalised as a result of stroke.	<i>Intervention one</i> 1. Information pack. <i>Intervention two</i> 2. Information pack plus instruction on how to read and understand the information.	C	RCT	2	P

Study, date, country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design	No. primary outcome measures	Success in primary outcomes**
<b>Mant 2000</b> <sup>190,191</sup> UK	323 patients with stroke and 267 carers.	<ol style="list-style-type: none"> <li>1. Visits from a family support officer. Number of visits individualised at their discretion (average of 1 hospital visit, one home visit and three phone calls over a six-month period).</li> <li>2. Information leaflets.</li> </ol>	A	RCT	4	P
<b>Mant 1998</b> <sup>192</sup> UK	71 acute stroke patients.	One-off mailing of an information pack containing Stroke Association publications delivered one month after stroke.	D	RCT	3	F
<b>Pain 1990</b> <sup>193</sup> UK	36 patients admitted to hospital with a CVA for at least 10 days and discharged home with a relative or carer.	Single mailing of a booklet containing information covering: persisting symptoms, aims of rehabilitation, instructions on daily living activities, exercises prescribed, local and national addresses/contacts for people with stroke.	B	RCT	3	P
<b>Rodgers 1999</b> <sup>194</sup> UK	204/398 patients and 176 carers.	<ol style="list-style-type: none"> <li>1. Six one-hour small group sessions for patients and carers delivered by a range of healthcare professionals covering stroke and consequences, the role of staff and caring for stroke patients.</li> <li>2. Leaflets and telephone hotline number for more information.</li> </ol>	A	Cluster RCT	1	F



Study, date, country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design	No. primary outcome measures	Success in primary outcomes**
Smith 2004 <sup>195</sup> UK	170/353 acute stroke patients admitted to hospital.	<ol style="list-style-type: none"> <li>1. Recovery manual covering stroke facts, financial benefits and relevant services. Single dose of intervention delivered in hospital.</li> <li>2. 20-minute review meetings with the multidisciplinary team to provide information about patients' progress, answer questions and develop shared rehabilitation goals. Frequency of meetings not reported.</li> </ol>	B	RCT	1	F
Tilling 2005 <sup>3,196</sup> UK	340/513 hospital and community stroke patients.	Home visits from a family support officer to provide information, emotional support and prevention advice to families and patients. Frequency and duration of support was tailored to the individual family.	A	RCT	1	F
Towle 1989 <sup>3,197</sup> UK	44 patients with depression ≥ one-year post stroke.	<p><i>Intervention 1</i></p> <ol style="list-style-type: none"> <li>1. Information booklet including addresses of stroke clubs, social services and OT departments; descriptions of financial benefits.</li> </ol> <p><i>Intervention 2</i></p> <ol style="list-style-type: none"> <li>2. Information booklet (as above).</li> <li>3. Twice-weekly visits from a social worker for 16 weeks (action depended on the individual).</li> </ol>	D	RCT	3	F

Study, date, country	Participants	Components, 'dose' & duration	Theoretical rating	Study Design	No. primary outcome measures	Success in primary outcomes**
van den Huevel 2000 <sup>198,199</sup> Netherlands	257 carers (130 group programme, 78 home visit, 49 controls).	<i>Intervention one</i> 1. Eight two-hour group education sessions. <i>Intervention two</i> 2. Four two-hour home visit education sessions. 3. Both interventions started four weeks after recruitment and lasted 10 weeks. Both were led by experienced nurses and included educational sessions, discussion on stroke causes and consequences and occupational therapy.	B	RCT	2	S

\* Design abbreviations: Randomised Controlled Trial (RCT); Quasi-experimental study (QE); time series controlled design (QE-TS); before and after study (BA); qualitative evaluation (Qual).

\*\* Outcome success: successful in all primary outcomes (S); partial success i.e. successful in at least one but not all primary outcomes (P); failure in all primary outcomes (F).

monitoring,<sup>151</sup> and multi-faceted interventions incorporating educational and psychosocial components.<sup>147,157,164</sup> Interventions to improve adjustment and recovery included information booklets/records,<sup>167,170,188,189,192,193</sup> education, training and counselling<sup>110,111,172-175,177,181-183,185,186,194,195,198,199</sup> and social or emotional support.<sup>9,75-90</sup> There were significant differences in the success of studies in different areas ( $\chi^2=12.64$ ,  $df=4$ ,  $p=0.013$ ). Interventions to improve recovery, in particular social support or information interventions were less likely to succeed, 12 (41.3%) failed compared to 3 (15.0%) primary/secondary prevention interventions and 3 (17.7%) professional interventions. However, prevention interventions and professional interventions were also less likely to have been evaluated using RCT methods (9, 45% and 6, 35% respectively compared to 24, 80% of interventions to improve recovery).

### *3.3.1. Theoretical grounding*

Theoretical grounding was difficult to establish from published reports since most studies presented only a brief introduction to the study area and an overview of the methods. Forty-two of the 67 studies reported some form of theoretical grounding for their intervention (Tables 2-4) but only 14 were judged to be theoretically well developed (an 'A' rating). Table 5 presents a list of theoretical research in support of the interventions. While most studies included some form of literature review, this was not necessarily in support of the chosen intervention. Only eight studies reported attempts to systematically review the literature or cited an existing systematic review. Nineteen studies referenced published theoretical frameworks to support their intervention choice (mostly from the psychological literature) and 13 conducted empirical research to inform intervention development.



**Table 5. Theoretical quality: summary of studies with theoretical support for interventions.**

Evidence from:	Studies
Systematic review	N=8 120,136,151,152,174,187,195
Published theoretical frameworks:	N=19
Family systems theory	120,154,170,172,173
Lazarus & Folkman/stress-buffer theories	179,184,198
Counselling-enabling/social problem solving theory	176,182
Self efficacy/health locus of control	177
Prochaska & DiClemente –‘ Stages of Change’	164
Weinstein - bias in health perception	158
Orem/Bobath - self care nursing (patient empowerment)	110,137,145
Chronic care model (patient-centred care)	147
Shared decision-making models	150
Rogers - Diffusion-innovation theory	142
Empirical Research:	N=12
Testing applicability of theoretical model	177,182
Testing intervention components	110,130,159,177,190,193
Canvas user views/ service needs	3,112,140,145,161,195

*3.3.2. Outcome assessment*

Study outcome measures are presented in Table 6. A range of single item questions, standardised/published scales (53 in total), or author-developed scales (15) were used.

**Table 6. Summary of primary outcome measures.**

<b>Measure:</b>	<b>Professional interventions</b>	<b>Primary or secondary prevention</b>	<b>Recovery &amp; adjustment</b>
Knowledge	N=7 128, 135, 138-141	N=7 154, 159, 161, 163, 165, 166, 200	N=9 172, 173, 187- 189, 192, 193, 195, 201
Psychological and social adjustment, perceived health-status, self-rated quality of life, social resources, confidence and self esteem	N=1 132	-	N=17 110, 111, 170, 171, 173, 176, 177 , 179, 180, 182, 184- 186, 190, 192, 194, 198
Satisfaction	N=1 126	N=2 154, 161	N=12 3, 111, 167, 168, 171, 173, 180, 1 82, 187, 189, 190, 193
Physical functioning, independence, disability in activities of daily living	N=1 132	-	N=8 170, 171, 174, 180, 187, 190, 193
Mood: anxiety and depression	N=1 132	-	N=8 110, 171, 177, 182, 184, 185, 187 , 190
Mortality, morbidity and institutionalisation	N=2 127, 143	N=6 146, 153, 155-157, 159	N=1 185
Changes in clinical practice	N=9 126, 128- 131, 135, 137, 138, 142	-	-
Health behaviour / medication use / adherence	N=3 132, 136, 145	N=7 146, 148, 150-152, 161, 164	
Physiological risk factor measures	-	N=6 146, 151, 152, 156, 159, 164	N=2 111, 183
Use/receipt of health and social services	-	N=3 154, 156, 160	N=2 178, 197
Health perceptions, attitudes, behavioural intentions	N=3 132, 140, 145	N=3 148, 154, 158	N=1 177

Measure:	Professional interventions	Primary or secondary prevention	Recovery & adjustment
Family functioning, carer burden/stress/competence	-	-	N=6 170,173,182,184,185,187
Global health outcomes	N=1 145	N=2 147,148	N=1 171
Patient choice/decision making	N=1 145	N=1 161	N=1 167

Author designed outcome measures (with or without validation) were mostly used to assess knowledge or satisfaction with care but also to assess self-rated quality of life, health expectations, ‘recovery-efficacy’, illness perceptions, assertiveness, decision-making and confidence. There was no association between type of measure (single item or scale), measure development (published or author developed) and study outcomes. Most studies used multiple measures to evaluate impact. Twenty-one RCTs and 16 quasi-experimental/observational studies listed three or more primary outcomes of interest with 10 RCTs and 12 non-RCTs listing five or more primary outcomes (Tables 2-4). Studies with large numbers of primary outcomes (5 or more) were statistically less likely to be completely successful than those with fewer outcomes (5, 22.7% compared to 17, 38.6%) but were also less likely to fail (2, 9.1% compared to 16, 36.4% respectively,  $\chi^2=12.1$ ,  $df=2$ ,  $p=0.002$ ).

### 3.3.3. Methodological quality

There were significant differences in the success of interventions using different evaluation methods ( $\chi^2=17.2$ ,  $df=2$ ,  $p<0.001$ ). Only 4/28 non-RCT studies distinguished between primary and secondary outcomes,<sup>111,137,153,160</sup> but all achieved at least partial success and 12 (44.4%) achieved all of their aims. One study conducted a qualitative



evaluation of a family nursing intervention concluding that all aspects of the intervention were useful but did not specifically test a hypothesis.<sup>120</sup> Ten (25.6%) trials were successful, 11 (28.2%) were partially successful but nearly half (18, 46%) were unsuccessful. Sixteen (41.0%) RCT studies included a power calculation; 6/21 RCT studies with multiple (>2) primary outcomes reported considering statistical power (Table 7). One study considered power for 4/7 primary outcomes and although it was still slightly underpowered (it did not reach the target recruitment figures) it was successful in influencing all of the outcomes for which power was estimated.<sup>185</sup> In the only study to consider power for all measures, the authors anticipated that the intervention would lead to a 25% difference between groups in all risk factor control outcomes.<sup>151</sup> The intervention did not have the anticipated impact, the authors concluding that risk factor control rates in the control group were better than expected and consequently that the study was underpowered.

Only one RCT study reported conducting any form of exploratory trial of the intervention prior to the main study. It was used to test the feasibility of implementing a telephone intervention to provide nursing follow-up to improve adjustment and recovery and to test the validity of outcome measures.<sup>182</sup> In one of the social support intervention studies, the authors had already conducted a RCT of one of the intervention components (the information pack)<sup>190,192</sup> that could be described as a pilot evaluation. The authors also conducted research to inform their power calculation prior to the main trial and this work could be defined as the “modelling phase” of development. However, since this was the only study that did so, the relationship between study quality and success is difficult to assess. Studies reporting a power calculation to inform trial methods were no more likely to have been successful than those which did not report considering statistical power.

Table 7. Methodological quality: consideration of statistical power.

Study & date	Outcome measures	Time point	Power calculation	No. recruited	Impact on primary outcomes
Allen 2004 <sup>147</sup> USA	Global ‘well-being’ (Five domain score developed by authors).	3 months post intervention.	96 patients gives 90% power to detect small to moderate effect sizes across the five domains $\alpha=0.05$ .	96	There was a significant effect size of 0.53 on the global test score. Effect sizes were significant on all domains.
Boter 2004 <sup>168</sup> Netherlands	Dissatisfaction with stroke care (Satisfaction with Stroke Care questionnaire - SASC-19).	6 months post discharge.	524 participants gives 80% power to detect a 50% reduction in dissatisfaction ( $\alpha$ not reported)	536	No statistical differences in dissatisfaction scores between groups except intervention patients had higher scores on role limitation.
Clark 2003 <sup>170</sup> Australia	1. Family functioning (McMaster Family Assessment Device – FAD). 2. Functional status (Barthel Index - BI). 3. Social recovery (Adelaide Activities Profile - AAP).	6 months post discharge.	30 families give 80% power to detect a 0.14 decline in FAD from pre-morbid state to 6 months ( $\alpha$ not reported).	62	FAD scores remained stable in the intervention arm but declined in the control arm. The BI was slightly higher for the intervention group than controls. The AAP was better in the intervention group than control group for domestic chores, household maintenance and social activities.

Study & date	Outcome measures	Time point	Power calculation	No. recruited	Impact on primary outcomes
Ellis 2005 <sup>151</sup> UK	Proportion of patients whose risk factors were 'on target': i. All relevant risk factors controlled; ii. BP < 140/85; iii. Smoking cessation; iv. Blood glucose < 8.0 mmol/L; v. HbA1c < 7.5%; vi. Cholesterol < 5.0 mmol/L.	Five months post intervention.	89 patients per group gives power to detect a change from 25% risk factor 'on target' to 50% ( $\alpha$ not reported).	205	After adjusting for baseline differences the intervention had no significant impact for any risk factors.
Forster 1996 <sup>176</sup> UK	Improvement in social activities (Frenchay Activities Index – FAI).	12 months post recruitment.	160-220 patients gives 90% power to detect a 4-point improvement in the FAI ( $\alpha$ not reported).	240	No significant differences in FAI between groups. Qualitative analysis revealed that aspects of the nursing role (concern, attention, empathy and interest) were valued by the patients and careers.
Harari 2004 <sup>66</sup> UK	Self reported bowel movements (BM) per week.	one, three, six and 12 months post intervention.	120 patients would give 90% power to detect a 54% increment in BMs/week ( $\alpha$ not reported).	146	Mean number of BMs per week was higher in the intervention group compared to the controls and persisted at 12 months. Self-rated normal BMs were also higher in the intervention group.



Study & date	Outcome measures	Time point	Power calculation	No. recruited	Impact on primary outcomes
<b>Kalra 2004</b> <sup>185</sup> UK	<ol style="list-style-type: none"> <li>1. Death and institutionalisation.</li> <li>2. Modified Rankin.</li> <li>3. Physical functioning (Barthel Index).</li> <li>4. Social functioning (Frenchay Activities Index - FAI).</li> <li>5. Anxiety and depression (hospital anxiety and depression scale - HADS).</li> <li>6. Caregiver Burden (Caregiver Burden Scale).</li> <li>7. Quality of Life (EuroQol).</li> </ol>	three & 12 months post stroke.	300 patients would give the study 80% power to detect: 1-point change in Barthel Index; 1.5 change in FAI; 1.5 in HADS; 2.5 in EuroQol; 1 point on caregiver burden scale ( $\alpha$ not reported).	268	No significant differences were found in mortality/ institutionalisation. Patients in the intervention arm had lower median HAD scores and higher median Euroqol scores. A higher proportion were less disabled and had low Rankin scores at 3-months.
<b>Mant 2000</b> <sup>190,191</sup> UK	Patient and carer outcomes: <ol style="list-style-type: none"> <li>i. Quality of life (Dartmouth Coop charts; SF-36);</li> <li>ii. Disability (Barthel Index &amp; Rivermead mobility index);</li> <li>iii. Handicap (London Handicap Scale - LHS);</li> <li>iv. Emotional health (Hospital anxiety and depression scale - HADS).</li> </ol>	Six & 12 months post stroke.	300 participants gives 80% power to detect: 7-point difference in the LHS; 2.5-point difference in the HADS; 7-point difference in secondary outcome: SF-36 ( $\alpha$ not reported).	323	Significant differences in carer FAI and some quality of life domains in favour of the intervention (5 parts of SF-36 and 1 part Dartmouth Coop chart). No significant differences in patient outcomes.
<b>Pennington 2005</b> <sup>142</sup> UK	Adherence to clinical guidelines (10-item tool developed by the authors).	Eight to 12 months post intervention.	24 departments recruiting 50 patients each gives 80% power to detect a 0.24 difference in adherence at the $\alpha = 0.05$ .	717	No difference between groups in adherence to practice guidelines.

Study & date	Outcome measures	Time point	Power calculation	No. recruited	Impact on primary outcomes
<b>PRISM 2003<sup>136</sup></b> <b>UK</b>	Relative risk reduction (RRR) in ischaemic and haemorrhagic vascular events achieved by antithrombotic therapy Vs no therapy.	Six months post intervention.	27 centres recruiting 40 patients each (1080 patients in total) gives 80% power to detect a 5% change in RRR, assuming an ICC of 0.15 ( $\alpha$ not reported).	1952	No difference in RRR between groups, or the proportion of patients receiving optimal therapy.
<b>Rodgers 1999<sup>194</sup></b> <b>UK</b>	Patients' and carers' perceived health status (SF-36)	Six months post stroke.	160 patients and 216 carers gives 80% power to detect differences ranging from 5-10 points in the subscales of the SF-36 ( $\alpha$ not reported).	204	No differences in SF36 outcome between groups.
<b>SAFIRE 2004<sup>143</sup></b> <b>Australia</b>	Fall rate.	Three months post intervention.	348 patients gives power to detect a 10% reduction in fall rate in the intervention group ( $\alpha$ and $\beta$ not reported).	715	Fall rates increased in both trial arms over the study period. No significant differences between groups.
<b>Smith 2004<sup>195</sup></b> <b>UK</b>	Knowledge score (developed by the authors).	Three & six months post stroke.	Sample size was calculated for secondary outcomes only; 65 patients per group were needed to achieve 90% power to detect a difference of 8 points in the London Handicap Scale ( $\alpha$ not reported).	170	No difference in knowledge score between groups at either time point.

Study & date	Outcome measures	Time point	Power calculation	No. recruited	Impact on primary outcomes
<b>Tilling 2005<sup>3</sup> UK</b>	Satisfaction with services (Pound Scale).	Three & 12 months post randomisation.	336 patients give 80% power to detect a 15% difference in satisfaction between groups ( $\alpha$ not reported).	340	No difference in overall satisfaction score between groups for either patients or carers. Satisfaction with some aspects of care was higher in the intervention group than the control group for patients and carers at particular time points but no consistent patterns.
<b>Van Den Huevel 2000<sup>198</sup> Netherlands</b>	<ol style="list-style-type: none"> <li>Confidence in knowledge about relevant themes related to being a caregiver (a new instrument developed by the authors).</li> <li>Use of active coping strategies (Utrecht Coping List).</li> </ol>	14 weeks from baseline.	<p>76 respondents per group gives 80% power to detect a medium effect in outcomes; 547 respondents per group would give 80% power to detect small effects (<math>\alpha</math> not reported).</p>	<p>130 group one; 78 group two; 49 group three.</p>	<p>Both interventions achieved small increases in confidence in knowledge of patient care and use of active coping strategies The group program achieved a small increase in social support seeking. No differences between home and group support.</p>



#### *3.3.4. Impact of study quality on outcomes*

After adjusting for aspects of methodological quality (study design and statistical power) there was no evidence that theoretical development was associated with success in primary outcomes. Six RCT studies were judged to be theoretically well developed and included a power calculation; two of these were successful,<sup>147,170</sup> two were partially successful<sup>182,187,190</sup> and two unsuccessful.<sup>3,194</sup> Of the two successful interventions, the first had a significant impact on family functioning, which remained stable in the intervention group but declined over time in the control group<sup>170</sup>; the second had a significant effect on an author-defined (and validated) global well-being score (0.53 effect size) but the implications of this for clinical practice are difficult to interpret.<sup>147</sup> Five non-RCT studies were also considered well developed; one of these was successful,<sup>47</sup> three were partially successful<sup>110,130,137</sup> and one did not test a specific hypothesis.<sup>120</sup> If the theoretically moderately well developed studies ('B' rated) and well developed studies ('A' rated) are combined, the findings remain the same with no clear evidence that theoretical or methodological quality was associated with improved outcome.

#### *3.3.5. Articles identified since the last search*

A recent search on complex intervention (28<sup>th</sup> July 2006) identified a further six intervention studies relevant to this review and it is important to consider whether inclusion of these studies would influence the main findings. The new studies included three interventions aimed to improve recovery after stroke: a nurse support worker intervention for patients and carers<sup>202</sup>; a web-based education and peer-led support intervention,<sup>203</sup> and an arts-based reading service for stroke inpatients.<sup>204</sup> Two interventions focused on primary and secondary stroke prevention (both stroke patients

and high risk groups): a pharmacist-led risk management intervention to improve management of atrial fibrillation<sup>205</sup>; and a nurse-led education and coordination intervention to improve risk factor management for patients after carotid endarterectomy.<sup>206</sup> One study evaluated a workbook and training intervention for community health workers aiming to improve risk factor management for African American women.<sup>207</sup> No interventions were rated as theoretically ‘well grounded’. Two studies did not conduct statistical evaluation of the intervention.<sup>204,207</sup> Of the remaining four, all were at least partially successful.

Two studies were evaluated using RCT methods.<sup>202,206</sup> Neither conducted a pilot evaluation and only one conducted a power calculation to estimate sample size requirements (Table 8). This study used six key outcome measures but estimated power for only one of these (depression) and was substantially underpowered. The study demonstrated partial success in influencing outcomes.

This analysis does not challenge the previous findings that few complex intervention studies are theoretically or methodologically well developed according to MRC recommendations. The findings do not help in understanding the association between methodological quality and outcome.

### **3.4. Discussion**

This review aimed to investigate theoretical and methodological quality in the development and evaluation of complex interventions in stroke care and the impact of this on study outcomes. The 67 included interventions investigated a range of health outcomes. The majority of interventions identified were targeted at an individual level (general public, stroke patients, care-givers and health professionals) rather than at a

Table 8. Methodological quality: considering statistical power (studies since the last search).

Study & date	Outcome measures	Time point	Power calculation	No. recruited	Impact on primary outcomes
Burton, 2005 UK <sup>202</sup>	<i>Patient outcomes</i>	Three and 12 months post stroke.	121 patients in each group required to give 80% power to detect a 50% reduction in depressed mood over 12 months; $\alpha=0.05$ two tailed significance).	87 intervention arm; 89 control arm. 126 patients followed up (total).	No consistent pattern but reduction in median BI was significantly greater for intervention group than controls for time period three to 12 months; improvements in median NHP score from three to 12 months significantly greater in intervention group; reduction in caregiver strain 3-12 months significantly greater for intervention than controls. No differences in change in BDL, FAI.
	1. Dependency (Barthel Index BI).				
	2. Perception of general health (Nottingham Health Profile – NIH).				
	3. Depression (Beck depression inventory - BDI).				
	4. Everyday activities (Frenchay Activities Index – FAI).				
	<i>Carer outcomes</i>				
	5. Carer Strain (Caregiver Strain Index).				



social or environmental level. This may reflect the chosen search criteria since environmental and social interventions are more likely to be targeted at the general population and aim to prevent a range of diseases. Such studies might not have been found unless they included stroke specific outcomes. In interpreting findings from this review, it is also important to note that the focus was solely on complex interventions for stroke and it is possible that intervention development in other disciplines is better, worse or different to the development of the interventions analysed here.

Observational or quasi-experimental studies tended to yield better outcome success than RCT designs. Differences may reflect difficulties in demonstrating success using RCT methods,<sup>208,209</sup> but may also be influenced by publication bias, since journals are more likely to publish studies if there is a significant treatment effect.<sup>46</sup> If journals are less likely to publish non-significant results for observational or quasi-experimental studies than for RCTs, then interventions evaluated in RCTs would appear to be less successful than those evaluated using other methods.

Study design may also explain the apparent lack of success of interventions focusing on patient and carer adjustment and recovery since these studies were more likely to be evaluated in RCTs. There were few RCT studies evaluating interventions in primary or secondary prevention, possibly reflecting problems of recruitment, randomisation and follow-up, for relevant community interventions. Such interventions may also present ethical difficulties due to the requirement that researchers withhold the intervention from some groups/patients.<sup>57,108</sup> For the studies included in this review, a number of novel quasi-experimental methods were used in an attempt to overcome such difficulties, including matched controls, time-lag controls, or 'before and after' studies, with or without qualitative evaluation.<sup>153,156,157,159</sup> However, the MRC Framework suggests that these methods are inadequate for evaluating efficacy since non-random

allocation of participants may lead to bias. Using the MRC Framework (with its focus on RCTs) as a marker of quality in complex intervention evaluation may lead to exclusion of those interventions which best serve the needs of disadvantaged groups (since these groups are more difficult to identify, recruit and retain in research studies).<sup>210</sup> It may also lead to exclusion of interventions that have the most impact on longer-term population health goals (such as mortality rates or behaviour change). Although, theoretically, longer-term follow-up is not a problem of RCTs, in practice RCTs are more difficult and expensive to conduct over long periods of time.<sup>87</sup>

One of the potential strengths of the MRC Framework is that it sets standards for theoretical and methodological development within a RCT design such as highlighting the importance of considering statistical power. However, a substantial proportion of the RCTs in this review did not include a power calculation to justify sample size. No relationship was found between reporting a power calculation and study success, possibly because many of the studies that did not conduct a power calculation were still adequately powered; conversely not all of the studies that reported a power calculation did achieve statistical power. Exploratory evaluations prior to the main study could have been used to make more realistic estimates of intervention impact. Authors could then have adjusted sampling or outcome measures at the outset.

For most of the studies there was little evidence that authors considered the theoretical development, or the mechanisms by which the intervention was expected to influence outcomes. However, this was not necessarily the fault of the investigators. For example in two social support intervention studies the interventions were existing services rather than services designed specifically for the study.<sup>171,180</sup>

Lack of clarity about the mechanisms by which interventions work, makes it difficult to pool the results of similar studies in systematic reviews or meta-analyses, since although



intervention components appear similar, we do not know whether interventions are delivering similar ‘packages’ of care. In one systematic review of problem solving interventions for carers after stroke, the authors concluded that poor theoretical and methodological quality coupled with a diverse range of intervention components made it impossible to draw conclusions about efficacy.<sup>211</sup> Similar problems have been reported in systematic reviews of other complex stroke interventions such as information and education.<sup>212</sup>

Requirements for study design and presentation of results inevitably change over time and this review is limited in that inferences about study development are based on published or reported information only. It is possible that some studies did actually conduct empirical work or pilot their interventions but did not report it.<sup>213</sup> However, it is concerning that so few studies reported an appropriate literature review or considered established theory. It would not be acceptable within a standard clinical trial to test out a pharmaceutical intervention in a phase III study without sufficient understanding of the mechanisms by which the drug influences bodily processes. Yet complex health service interventions seem to be developed based on ad-hoc assumptions and evaluated using methods where at the end of the study it is impossible to understand the reasons for success or failure.

Complex interventions often aim to influence a number of outcomes, or outcomes that are difficult to encapsulate in a single measure. In just over half of the studies multiple outcome measures were used. In some cases, authors may have incorporated multiple measures in the hope that by ‘hedging their bets’ it would enhance the chance of at least one of the measures showing a significant result. Non-RCT studies were particularly poor at specifying the main outcomes of interest and this may also explain why they were less likely to have failed. However, not identifying the key outcomes of a study in



which multiple outcomes are assessed suggests poor theoretical development and that the study question itself is insufficiently clear.

Whether using the recommendations of the MRC Framework to assist development will improve our understanding of interventions in the future is unclear. There did not appear to be any convincing evidence that being theoretically or methodologically well developed improved outcomes. The one study that explicitly reported using the MRC Framework in development was unsuccessful.<sup>3</sup> The Framework does not guarantee success but in the case of this intervention, despite apparently following recommended procedures we are still no clearer about why the intervention failed. An evaluation of intervention implementation (process evaluation<sup>95,115</sup>) could have enlightened our understanding.

#### *3.4.1. Summary*

In this chapter the MRC Framework was used to retrospectively assess theoretical and methodological quality of previous intervention studies in stroke. The implications of these findings for future complex intervention development and for the application of the MRC Framework are discussed further in Chapter 10. For the remainder of the thesis I investigate prospective application of the MRC Framework in guiding intervention development.

## **Chapter 4. Methods for investigating application of The Framework**

### **4.1. Introduction**

In this chapter I present an outline of the methods for investigating how the MRC Framework<sup>1</sup> was used to develop and evaluate the Stop Stroke intervention. Specific methods were used to investigate particular phases of The Framework, thus the methods are presented under separate section headings. The combined findings are used to understand the overall use of The Framework as a research tool and in exploring the wider social and political context in the discussion presented in Chapter 10.

The theoretical phase of Stop Stroke development (Chapters 5 and 6) incorporated a range of methods including statistical analysis of the South London Stroke Register (SLSR) and qualitative research with stroke patients, carers and professionals. Since the focus of this thesis is to explore the use of qualitative methods in intervention development and evaluation, here I outline only the qualitative methods used. Details of the methods for the quantitative studies are presented in the published findings from SLSR analysis<sup>34,214,215</sup> (see also Appendix 1).

To investigate the modelling, exploratory trial and definitive RCT phases of Stop Stroke development I used an ethnographic approach.<sup>216,217</sup> This involved using a range of data collection and analysis methods including participant observation, diaries, informal discussion with staff, in-depth interviews with key informants and semi-structured interviews with stroke patients. A chapter-by-chapter outline of the methods for each research component is presented below.

## **4.2. Methods for investigating patients' and carers' experiences and understanding of secondary prevention**

To investigate secondary prevention from the point of view of the patients and carers themselves (Chapter 5) I used in-depth interviews. The choice of methods for this part of the research was pre-defined (by the other Stop Stroke investigators and me) since these interviews were conducted as part of Stop Stroke intervention development. However, the work remains relevant to this thesis since I am presenting it as a case study for how in-depth interviews can be used to inform intervention development. Ethics approval for this part of the research was obtained from Guy's and St Thomas' Hospitals ethics committee as part of the Stop Stroke study.

### *4.2.1. Identifying the patients and carers*

Since the investigators also managed the ongoing SLSR, the register provided a convenient and appropriate sampling frame from which to identify patients for in-depth study. The SLSR is a prospective inner city population based register of stroke incidence since 1995. At the time this research was conducted, the SLSR covered 22 wards of North Lambeth and North Southwark, an estimated population of 234,533.<sup>17</sup> It collects data on patients' socio-demographic characteristics, health service use and risk factor control at various time points (prior to the stroke, at three months and one year post stroke).

Previous statistical analyses of SLSR data on risk factor management conducted as part of the intervention development process were used to inform sample selection.<sup>34,214</sup>

Existing statistical coding from these studies was used to classify patients into categories according to their risk factor control, for example to identify those with physiological and behavioural risk factors at the time of stroke (atrial fibrillation,



hypertension, diabetes, smoking, heavy alcohol use and obesity). Similarly, statistical coding from these studies was used to identify patients suitable for particular pharmacological therapies (aspirin, warfarin and antihypertensives) and to categorise patients according to their subsequent risk factor control (tablet taking and change in behavioural risk factor control since the stroke).<sup>34,214</sup> Lists of patients were produced for each category and used to select a sub-sample of patients for interview.

Originally the aim of the research team had been to use extreme or 'deviant case' sampling<sup>218</sup> (p230) to compare experiences of secondary prevention between a group of patients defined as having 'optimal' risk factor management and a group defined as having 'poor' risk factor management. The lead stroke clinician felt that most of the patients under his care could be classified as either having good secondary prevention management or poor secondary prevention management. In practice, classifying patients into extreme categories according to the SLSR data was not as straightforward as anticipated. For example patients might have one risk factor managed and not the others. It proved impossible to select two comparable groups for interview, in particular because so few patients fell into the 'optimal' risk management category.

Instead maximum variation sampling<sup>218</sup> was used to select a non-random heterogeneous sample of 20 people with a range of socio-demographic and risk factor characteristics requiring different types of secondary prevention management. The selection of patients for interview evolved from the previous analyses of the SLSR. We had demonstrated that particular groups (older patients, those with more severe disability and those from White ethnic groups) had poorer control of particular risk factors (for example White stroke survivors were more likely to continue smoking, drink heavily and were less likely to be taking recommended medication).<sup>34,214</sup> This information was used to help guide sample selection. It was also hypothesised that different risk factors would raise

different management issues. For example risk factors treated with over the counter medication would present different challenges for secondary prevention to those treated with prescribed medication. Thus sample selection was designed to include participants with a diverse range of risk factors and management strategies.

#### *4.2.2. Consent and data collection*

Interviews took place between September 1999 and January 2000. I contacted each patient by telephone and invited them to participate in an interview in their own home. I explained that the study aimed to help people who had already had one stroke, from having further strokes and that I wished to discuss their experiences since the stroke: what had happened to them; the health services they had received; and their views on preventing further strokes.

I used a topic guide of open-ended questions rather than a structured questionnaire to guide the interview so that patients would have the opportunity to discuss secondary prevention in the context of their own experience rather than providing responses to pre-specified questions. There is considerable support for the use of in-depth interviews in this context and they have been used previously to investigate patients' experiences of stroke.<sup>219-222</sup> I asked patients about a range of topics covering their experiences of secondary prevention since the stroke and their understanding of secondary prevention. For a list of topics covered see Appendix 2. If patients raised issues relevant to secondary prevention I asked them to discuss these in more detail, or took notes and revisited the issues later in the interview.

Family members or 'informal carers',<sup>223</sup> were also sometimes present during the interviews and in such cases they were also invited to participate. It is commonly reported that stroke patients rely on informal carers for physical and emotional



support,<sup>24,223,224</sup> and I hypothesised that carers would also play an important role in secondary prevention practices. Their contributions were considered not as a 'proxy' for the opinions of the stroke patients themselves but provided additional insights into the challenges for secondary prevention management.

#### *4.2.3. Interview analysis*

All interviews were audio taped and then transcribed in full. Audio taping is recommended for recording interview data since it allows better flow of conversation, enhances validity of data and speeds up the interview processes (p146).<sup>225</sup> In one interview the patient asked not to be recorded since she felt embarrassed about her communication difficulties and in this interview I took detailed field notes, which I later wrote up for analysis.

There are no hard and fast rules for analysing this type of qualitative data but most authors recommend a process of 'coding up',<sup>226</sup> that is organising the data into categories or themes and reorganising them to tell a coherent 'story'.<sup>227</sup> Analysis of the patient interviews involved reading each transcript and coding phrases, sentences or paragraphs of text into summary codes. Data were ordered by placing similar codes together under broader categories and were then linked to an overall theme.<sup>228</sup> This process was circular, with codes and categories checked against original transcripts to ensure they represented the views of participants and that discourse was not taken out of context of its original meaning.<sup>vi</sup>

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<sup>vi</sup> Further discussion of analysis methods is presented elsewhere: analysis of interviews to explore patients' and carers' understanding of secondary prevention, p113-4; analysis of field notes to investigate delivery of secondary prevention, p95 and p142-4; analysis of field notes to investigate the process of intervention development, p96-7 and p171-2; analysis of field notes to investigate evaluation of the intervention, p101-3 and p212; analysis of interview data to explore the impact of the intervention, p108-9 and p259. The coding process was conducted manually as described above. The codes emerged from the data rather than being driven by previous theory. At the time the research was conducted funds were



#### 4.2.4. *Validity*

There is little consensus concerning the best way to ensure validity in qualitative analysis. To ensure quality in interviewing, the first two transcripts of the interviews were checked by a third party (CM). The coding process was not conducted separately by multiple researchers as some recommend.<sup>229</sup> However, the process and categories generated were discussed with CM during analyses.

Some suggest that theme 'counts' should be presented as an indicator of the weight of each theme identified,<sup>230</sup> otherwise known as content analysis.<sup>231</sup> Others suggest the use of different research approaches or methods to 'corroborate' the findings through triangulation.<sup>232</sup> However, content analysis can be criticised in this context for its assumption that the number of times a theme arises is indicative of its importance. This positivist approach to analysis may not be appropriate for assessing qualitative data generated using alternative epistemological assumptions (p191).<sup>233</sup> Triangulation may also present problems for establishing validity since combining multiple methods can often lead to confusion rather than consensus in interpretation.<sup>216</sup> Instead I used two methods to try to enhance the validity of these findings, negative case testing,<sup>218</sup> and respondent validation,<sup>234</sup> (feedback of findings to stroke patients). Negative case testing involved seeking cases that did not fit the emerging categories and considering alternative explanations for patients' experiences and understandings.<sup>218</sup> I fed back the findings of the interviews to stroke patients and carers in two contexts: at the Caribbean

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not available to use a computerised qualitative data analysis package. However, after subsequently completing a course on the software package NVivo, I decided that this would not enhance rigour or validity and continued with my own method of analysis. The main themes emerging from this interview analysis are outlined on p114 and include: health service management of secondary prevention, understanding of the causes of stroke (preventability), priorities after stroke and the way stroke is conceptualised as an acute event or chronic disease.

Medicine conference in 2000 and to the Stroke Research User Involvement group in 2006 set up as part of a local stroke service modernisation initiative.<sup>235</sup> This is not strictly respondent validation (p156)<sup>234</sup> since I did not feed back the findings to those who had originally taken part in the interviews but this did at least ensure that those who had experienced a stroke could comment on my interpretations. In practice the participant feedback was supportive of the findings, with participants commenting on how their experiences concurred with particular themes. However, there were ethical concerns about what I had done in instances where problems with management had been identified (for example what I had done in response to a patient with depression not feeling that she could leave the house anymore). The ethical challenges of conducting qualitative research studies will be discussed further in the methods sections presented below and in Chapter 10.

#### **4.3. Methods for investigating secondary prevention delivery in the stroke clinic**

To investigate delivery of secondary prevention on risk factor management after stroke (Chapter 6) I used a different type of qualitative method, non-participant observation at two stroke outpatient clinics in inner city London. Non-participant observation is not a clearly defined method but may include the recording of quantitative or qualitative data or both. It has been previously used in clinical research to investigate the process of acute stroke care.<sup>236</sup> In the context of this research I used the method to observe the delivery of stroke secondary prevention delivery in its natural setting (the consultation) but without participating in the interaction itself. Non-participant observation had the advantage that I could study secondary prevention as it occurred rather than simply relying on patients' or professionals' reports of what happens. I already had an insight into patients' perspectives on risk factor management but since secondary prevention



was not a particularly meaningful concept, patients themselves had little insight into why they had or had not received secondary prevention services.

As with the research presented in Chapter 5, the work was conducted primarily as part of the Stop Stroke study. However, it remains relevant to the PhD since it represents the use of alternative types of qualitative method to inform intervention development.

#### *4.3.1. Sampling*

Ideally it would have been desirable to observe secondary prevention practice in the primary care setting in addition to the outpatient setting since secondary prevention requires long-term management of risk factors in the community. However, this presented practical difficulties given the small number of stroke survivors visiting any one GP (each GP is estimated to see approximately one to two stroke patients per year) and the impossibility of knowing when a stroke patient might present to his/her GP. By contrast, stroke clinics had the advantage of large numbers of stroke patients attending at a regular time.

Initially observations were to be conducted at only one elderly care outpatient clinic (clinic one), which represents the most common environment for care of stroke patients in the UK.<sup>237</sup> Theoretical sampling was used, with consultations observed over sequential weeks and data analysis starting while observation was ongoing. Data collection at clinic one was terminated after 10 weeks when observations ceased to provide data on new concepts. Once analysis had begun it appeared that some findings might be specific only in the elderly care context. For example, as others have highlighted, if clinical management is influenced by intellectual interest then health professional reactions to aspects of management may differ between specialties.<sup>238</sup>

Equally, since previous studies have shown that patients' understanding of future risk is



influenced by the embodied experience of stroke,<sup>239</sup> it was hypothesised that patients' residual disability caused by the stroke might influence interaction in the consultation. This was also supported by the SLSR analyses.<sup>34,214,215</sup> Thus the research team decided to conduct observations at a second clinic. The TIA and minor stroke clinic (clinic two) was chosen because the team had links with a clinician at a local clinic who was interested to take part but this forum also provided a suitable contrast to clinic one. It was anticipated that patients attending this clinic would have less severe symptoms and that there would be a larger proportion of younger patients who might not have access to elderly care services. Data collection at clinic one took place between January 2001 and April 2001. Data collection at clinic two took place from September 2001 until January 2002.

In justifying the methodology, it is important to consider whether observation of only two specialist clinics was likely to provide findings representative of other secondary prevention services provided in less specialised settings. The study aimed to represent the clinics and health professionals concerned but were not necessarily representative of all secondary prevention services. However, since observation involved national stroke experts delivering secondary prevention in a specialised setting (the 'best case scenario' for stroke care) it is likely that theoretical issues for development of services raised from these observations will be at least as important if not more important in less specialised settings.

#### *4.3.2. Consent*

Consent to participate was obtained from consultant physicians at the outset; junior doctors whose consultations were observed were asked for consent to participate at the start of each clinic. At the start of each consultation the professional introduced me (the

observer) to the patient and any accompanying relatives, friends and carers. He or she then explained the purpose of the research and if the patient agreed to participate, I remained in the consultation room sitting to one side of the participants in order to minimise interference in the usual doctor-patient interaction. In some exceptional cases I was asked to join in the consultation (I was asked direct questions by the professionals or patients or I was asked to assist the professional in his/her practice).

#### *4.3.3. Data recording*

I used a structured observation schedule to record participant characteristics including skill mix of health professionals, age, ethnicity, mobility and risk factors of patients; and consultation characteristics including length of consultation and patterns of questioning (Appendix 3). The observation schedule was designed by me guided by observation of two clinics prior to the main study. I also took detailed hand written field notes on the context of the consultation and content of the discussion between health professional and patient. Details of discussion between different health professionals and informal comments made outside the formal consultation but relevant to the consultation were also noted. I did not aim to ask direct questions of health professionals but in some cases the professional continued to discuss aspects of secondary prevention with me after the consultation had finished and in such cases I added these discussions to my notes since it helped to contextualise the clinic discussions. Field notes were written up directly after the consultation to enhance validity of data and key points about the interview documented.

In hindsight it may have been helpful to interview the professionals after each clinic since this might have provided additional insights into their understanding of secondary prevention. However, practically it would have been difficult to interview professionals



after each consultation or even each clinic given the time constraints of the busy clinics. Equally, since I was using a 'non-participatory' approach I did not wish to intervene in any way that might influence professionals' practice in subsequent consultations (the Hawthorne effect).<sup>216</sup> It is also questionable whether such interviews would have helped in interpreting professionals' management strategies since what people say and what they do in practice are often not the same.<sup>104vii</sup> Field notes were chosen as the method of data collection rather than audio taping since this allowed me to contextualise discussions between doctor and patient including details of non-verbal interaction between professional and patient. I also felt that hand written field notes would cause less interference with consultation processes than other methods such as video taping which might have inhibited dialogue between patient and professional. Taping alone would have prevented capture of interaction between patients and professionals outside the consultation room (such as in the examination room, corridor or other consulting room). In practice, it became clear that my sitting in the consultation room recording field notes did interfere with the usual consultation:<sup>216</sup> I was asked questions by participants; in one consultation I was asked not to observe the consultation by the professional; and in one consultation I was asked to stop recording field notes by the patient's son. There were also examples of the professionals altering their practice as a result of my presence (this is discussed further in Chapter 6). Thus in hindsight it may have been more appropriate to have audio taped the interviews to increase data validity since tape-recording is strongly recommended for recording human interaction.<sup>240</sup>

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<sup>vii</sup> As part of the Stop Stroke development process I conducted interviews with two consultants and two junior doctors about their understanding of secondary prevention. However, participants' responses more closely reflected perceptions of appropriate practice rather than the doctors' own practice. Thus adding interview methods to help interpret the observational data may have raised more questions than it resolved. However, this would be an interesting area for further study.



#### *4.3.4. Analysis*

Field notes from the two clinics were analysed for emerging themes (as described in the methods section for Chapter 5). Data from each clinic were first analysed separately to explore similarities and differences in secondary prevention delivery between the clinics. However, although the demographics of clinic participants and the structure of the consultation differed between clinics, there were more similarities than differences in the way secondary prevention topics were discussed and so data were subsequently merged and analysed together.

#### *4.3.5. Validation of findings*

Copies of findings were sent to the consultants at each clinic for respondent validation together with a summary of the key points. Consultants were asked to provide comments and to highlight anything they were not comfortable with. Only consultant one provided comments, which included saying that he felt embarrassed when reading through some of the quotations of dialogue (and the language used) in the clinics. He also queried a statement made about professionals being 'subjective' in their approach to risk factor management. As a result of the comments I revisited the findings and the original data before making some changes. This did not however, result in marked changes to interpretation.

### **4.4. Methods for evaluating application of The Framework in development**

In Chapter 7 I present the first part of the process evaluation of intervention development and evaluation conducted specifically to explore the use of the MRC Framework as a tool for guiding development. For this investigation and that presented in Chapter 8 I used an ethnographic approach incorporating a range of methods

including participant observation. Ethnography is a commonly used method within social science research but its use is relatively novel within public health, although there have been some recent examples of ethnographic studies of intervention development.<sup>89,113,116</sup>

#### *4.4.1. Data collection and analysis*

The principal method of data collection for this investigation involved participant observation. Data collection started when I began working on the Stop Stroke study in March 1999 and continued until the start of the definitive RCT on 21<sup>st</sup> July 2003. I was also able to collect some data retrospectively, since the investigators gave me access to documents on study development that were written prior to my joining the study. These included documentation of meetings, emails, letters, presentations (overheads, power point slides), posters and informal correspondence (memos, notes) related to the study from 1999-2003. From the start of my PhD in 2001 I also kept a diary of Stop Stroke processes. Diaries have a strong history within anthropology as a tool for recording and representing fieldwork (see for example Geertz<sup>241</sup>) and in my case the diary included a record of events, instructions, decisions and my own thoughts on the trial. I also recorded details of study participants, their skills, roles and responsibilities in relation to the study. Specific time points did not influence my recording; rather I made notes or expressed thoughts when important events had occurred. This mode of recording inevitably influenced the type of data collected and has also influenced my interpretation of events since I was more likely to write in the diary if there was something I felt strongly about. In hindsight this seemed to happen more often when I was unhappy with something or someone or when I identified problems than when things were running smoothly. It is likely that my interpretation of processes will reflect



better the difficulties of intervention development rather than the process of intervention development per se.

I organised diary and documentary data chronologically for analysis. As with the previous two chapters, I analysed the data for themes relating to the process of intervention development and the use and impact of the MRC Framework. I produced a timeline of key events and processes, which I coded and categorised into broader themes influencing intervention development.

#### *4.4.2. Justification of my position as both intervention developer and evaluator*

Given that my position within the research team is fundamental to how the findings are interpreted, I feel that it is important to be reflexive and include upfront a discussion of my position as both intervention developer and evaluator within the team.

Being both the key researcher on Stop Stroke intervention development and the evaluator is unusual within the context of public health research methods. However, it meant that I was a true participant observer and had a number of advantages in terms of allowing me access to the development processes.

Bruyn (1966) identifies six criteria for ensuring quality in ethnographic work, defined as the 'Humanistic Approach' (Bruyn in Fielding 1993).<sup>227</sup> These include: i) amount of time the researcher is in the setting; ii) the physical location of the researcher in relation to the group studied; iii) variation in status of participants and activities observed; iv) familiarity with language; v) how close one is to the participants in terms of social relationships and vi) allowing participants to comment on interpretations of data. As an insider my ethnographic study fulfilled many of these recommendations. Apart from the first nine months of the trial (Chapter 9) I was located on site, had close working relationships with trial staff and investigators from junior researchers to senior



investigators throughout intervention development and evaluation. Before conducting analysis I had worked with all core investigators for over six years and trial staff for over two years and was familiar with team and trial language. I had regular contact with the principal investigator and other investigators on the study; I had conducted all the data collection and analysis for the research components of intervention development (theoretical phase); I was involved in discussions and meetings to decide on intervention design; I was involved in developing the intervention components (modelling phase); and I assisted in pilot testing the intervention (exploratory trial phase). Since I was part of the stroke team I also had close relationships with those working on the SLSR (involved in data collection for components of the intervention) and the team statisticians involved in designing the RCT evaluation.

Being a 'true' participant observer may also have resulted in a number of disadvantages. For example some might argue that as a true participant in intervention development it is not possible for me to also evaluate my own and my colleagues' work. Reflexivity is a strategy designed to overcome such problems, that is understanding how one's own experiences and background influence our understanding of phenomena.<sup>218</sup> I will go on to discuss this and the difficulties of being 'reflexive',<sup>242,243</sup> in this context but at this stage I would argue, as others have, that only by making a 'practical contribution' would it have been possible for me to gain the insight into the development processes that I did. As an external participant I would have seen only a 'filtered' version of such processes.<sup>244</sup> The challenges of gaining trust and access and the importance of insider-outsider relations within the context of programme development have been discussed elsewhere, for example by Knox in her study of a web design company specialising in online advertising campaigns<sup>245</sup> and by Mosse in his study of an aid programme to develop a poverty focused rain-fed farming project in India.<sup>244</sup> Both Knox and Mosse

highlight how the data they gathered were influenced by their positions within the respective organisations and their contributions to the work of these organisations. In Mosse's study he was both a consultant anthropologist working for the programme and a researcher investigating the programme. He argues that as an 'insider' working within the team, he had access to programme information not available to 'outsiders'. He cites Kaufmann (p112)<sup>246</sup> in explaining how as an 'outsider' access to certain sorts of information is limited:

'junior staff withhold or reveal information strategically in order to conceal poor performance or to negotiate position in the organisation or with outsiders...while professionals and bureaucrats hide behind official models and policy jargon' (p12).<sup>244</sup>

Certainly within my own previous experience of interviewing junior and senior clinicians to gain feedback on Stop Stroke development (Chapter 7), these ideas rang true. When I asked about their opinions of the importance of various secondary prevention strategies the junior clinicians were unwilling to put forward opinions until they knew what the senior clinician had advised; the senior clinician did not express opinions at all and simply repeated what was published in recommended guidelines.

#### *4.4.3. Ethical and methodological challenges*

My closeness to the study provided me with opportunities for investigation that would not otherwise have been possible had I been external to the team (access to people, documents and processes). However, this 'closeness' to the study also presented me with some ethical and methodological challenges including problems of 'reflexivity' and confidentiality. My first challenge in conducting participant observation in this context was my ability to be 'reflexive' about my own work. The process of reflexivity can be defined as the:



‘process of reflection that researchers using qualitative methods go through so as to document how the research process in general and often themselves in particular construct the object of research.’<sup>247</sup>

In other words, my ability to step back and look objectively at something I have a strong vested interest in protecting. Being reflexive and acknowledging the influence of one’s own subjective political and cultural standpoint in interpreting observations is now ‘comfortable convention’ within social anthropology.<sup>248</sup> Many texts have raised the problem of how their participation in the group/culture studied influenced their understanding and interpretation of that culture. In my case I was already a participant in the study before I began to observe, in other words, I was required to observe my own work. As an outsider (as in a ‘standard’ anthropological study) I would have had no status within the team. However, as a study participant I already had roles, responsibilities and interests as a junior researcher that conflicted with my ability to evaluate the study in an objective manner.

In addition I found that this type of participant observation presented challenges for critiquing the work of my colleagues and supervisors. Although the study group was large in the context of a single research project, it was still small in absolute numbers. Thus it was relatively easy for members within the team (and possibly externally) to identify the thoughts and actions of other team members when reported as a descriptive account (for example there is only one trial coordinator and only one principal investigator). Even if quotations or descriptions were anonymised it still poses ethical challenges and problems for confidentiality. Being a work colleague allowed me a privileged position, making it easy to gain the trust of colleagues at an early stage. This may have encouraged participants to reveal thoughts or actions, which they would not routinely have disclosed had I not also been a team member. All team members were aware of the evaluation and my role as evaluator from the start of the study. But, being a



work colleague may have made me less ‘visible,’<sup>245</sup> such that trial team members no longer realised that their disclosures could be made public.

The status of the core investigators in the study is also likely to have had an influence on my data collection and interpretation. No matter how objective I may have wished to be, the core investigators had the ultimate decision over how Stop Stroke events are analysed and published. It was not in any of our interests to present findings that reflect badly on them, the intervention, the trial, or me.

The ethical dilemmas listed above presented ongoing challenges throughout the course of the study; the details of which (together with my solutions) are discussed further in the subsequent chapters.

#### **4.5. Methods for evaluating application of The Framework in evaluation**

In Chapter 8, I continue presenting findings from the process evaluation, this time focusing on the conduct of the trial and intervention implementation after the trial started on 21<sup>st</sup> July 2003. The process evaluation and data collection will be ongoing to the end of the trial but for the purposes of this PhD, analysis focuses on the first two years to the end of July 2005.

##### *4.5.1. Data collection and analysis*

I continued to collect and organise data using the chronological diary method outlined in the previous section, recording minutes of meetings, field notes on discussions with the investigators and trial staff, collating documents and correspondence related to the study and recording my own thoughts on trial progress. However, my role as the participant/onlooker changed over the two years. According to the trial investigators, I

was no longer responsible for aspects of trial process. I also went abroad at the start of the trial for nine months and so was unable to see first-hand how the trial was operating. To investigate the trial operations and clarify observations from the point of view of the key staff, I conducted in-depth interviews with the trial coordinator (TC) and trial researcher (RA) at three time points: July 2003, just after the start of the trial; August 2004 one year into the trial and September 2005 two years into the trial. As with the patient interviews I had conducted for Chapter 5, a topic guide was used to investigate trial process (Appendix 4). Topics included the researchers' roles and responsibilities, their understanding of the intervention, their understanding of trial process, their experiences of conducting the trial, any problems that had arisen and how these problems had been resolved.

During year one of the trial (while I was abroad) the TC and RA were also asked to keep their own diaries of trial processes (Appendix 5). Diary format was slightly different from my own trial diary, consisting of one-page sheets with headings under which trial staff could record details of progress, raise issues, or list problems encountered and subsequent solutions. The headings included recruitment issues, data collection problems, trial process issues, computer programme failures and any other issues. The coordinator and researcher agreed to complete the diaries on a weekly basis and to email them to me overseas. I encouraged the trialists to write down anything they felt important. The diaries were also emailed to one of the core investigators in the study.

As in Chapter 7, findings from evaluation of the first two years of the trial were organised chronologically; trialists' diaries and interview findings were incorporated alongside my own diary records. Evaluation data were analysed for themes as in Chapter 7.

In addition to diary and interview data, for this part of the process evaluation I also used data from the SLSR and trial monitoring data to investigate trial recruitment and intervention delivery.

#### *4.5.1.1. Identifying potential trial patients*

The SLSR was used to identify patients who would potentially be eligible for the trial. The SLSR uses 12 overlapping sources of notification to identify potential first-in-a-lifetime stroke patients. The most common sources of notification are: hospital wards, death certificates and hospital medical staff.<sup>17</sup> Once identified each potential stroke patient is assessed by a trained researcher, to ascertain whether or not they have had a first stroke. Stroke is defined using the World Health Organisation classification described in Chapter 1.<sup>10</sup> If they are found to fulfil the eligibility criteria for the SLSR the researcher approaches them to participate. The researcher also assesses whether or not the patient is eligible for the Stop Stroke Trial. This process and the eligibility criteria for inclusion in the trial are discussed in more detail in Chapter 8.

#### *4.5.1.2. Trial recruitment and intervention delivery rates*

Trial recruitment was measured using SLSR data and data from a separate trial monitoring database. Recruited patients were those who fulfilled the trial eligibility criteria, gave consent to participate and who were successfully randomised into either the control or intervention arms. Monthly recruitment rates were estimated based on the number of recruited patients over the number of potentially eligible patients within a given month.

Intervention delivery was recorded using the trial monitoring database. The database contained information on each patient's SLSR identification number and the arm of the



trial to which the patient had been allocated. For those in the intervention arm, trial staff recorded the dates when intervention components were delivered, or if not delivered, details of the reasons why not.

Changes in monthly rates of recruitment and intervention delivery were investigated using  $\chi^2$  tests for association.

#### *4.5.1.3. Follow-up rates*

Follow-up of trial patients was also recorded in the trial monitoring database. To estimate trial follow-up, monitoring data were merged with SLSR data. Follow-up rates were calculated based on the proportion of patients who received a one-year follow-up visit by the SLSR team to collect outcome data for the trial.

#### *4.5.2. Ethical and methodological challenges*

In practice although the trialists' diaries were useful to a certain extent in documenting events during the trial, in most cases the researchers did not document issues as they arose. The trial researcher in particular would go for weeks without completing and sending her diary and was regularly chased by investigator one and me. When her diaries did arrive they were usually left blank or stated 'no problems'. A retrospective analysis showed that problems did arise but the diaries were not used to record them. In the interviews conducted in 2004 I asked both participants whether there had been problems with the diaries. They both indicated that they felt that the diaries were being used as a method of surveillance rather than as a research tool or a place to document worries or problems. The diaries also took extra time adding to their workload. Although I had gained their confidence in reporting trial problems verbally, this did not apply to written statements as this comment from the TC illustrates.

It was more like a reporting. I couldn't let loose on the diary if you know what I mean. I will let loose on a conversation or an appropriate forum but I'm not going to write – I don't have the space, I don't really have the time and space to write down all the little different rubbish that happens [TC 2004]

Written statements present a more formal account of the individual's thoughts or actions. Both the RA and the TC felt that the interviews were a safer environment for them to discuss trial concerns. In September 2004 after I had returned to the team I asked that the diaries be stopped.

As in the previous section, other methodological and ethical issues arose from using participant observation to investigate a study in which I had a vested interest. The diaries themselves presented one such problem in that when I did uncover problems with the trial (through diary or interview) I found it very difficult not to intervene to improve the trial process. Burr presents a detailed discussion of a similar ethical dilemma arising from participant observation conducted with street children and orphans in Vietnam.<sup>249</sup> In her work, she uncovered evidence that the children in her study were infected with HIV and were unknowingly spreading the virus amongst their peers. HIV transmission was not the focus of her own study but she felt it unethical not to attempt to intervene to prevent infection. In the Stop Stroke Trial the consequences of intervening or not intervening were not so life or health threatening as in the Vietnam study but the dilemma was the same. I had evidence that the trial staff did not fully understand aspects of the intervention or trial that might potentially prevent the intervention from working. I also had evidence that trial staff were unhappy with the support they were receiving. I felt that I was able to resolve these problems and found it difficult to ignore 'cries for help' when they were expressed. If the trial process or intervention delivery were inadequate this might influence intervention success, have a detrimental impact on the trial patients themselves and consequently our ability to

publish findings. I did not feel that methodological ‘purity’ was a sufficient excuse not to intervene. These challenges may illustrate the limitations of conducting participant observation as an insider, or alternatively illustrate the potential benefits of using participant observation alongside a RCT. Which answer is right depends on the research context and one’s epistemological standpoint. These issues are discussed in more detail in Chapters 8 and 10.

#### *4.5.3. Validation of findings*

My role as both observer and participant also raises challenges for validation of findings. Respondent validation is perhaps particularly important in this context, since as discussed above, the findings pose ethical challenges and the data may have a negative impact on the investigators. However, feedback to trial staff while the trial is in progress may also influence trial process, or intervention delivery in a similar way to reporting interim findings.<sup>65</sup> In this case, findings from the research have been fed back to the core investigators (the principal investigator and investigator one) who are not responsible for intervention delivery. Their comments have been incorporated into the discussion and findings will be fed back to other team members once intervention delivery is complete.

#### **4.6. Methods for evaluating the impact of the Stop Stroke intervention.**

Data for the final results chapter are also drawn from in-depth interviews with stroke patients and carers, this time to explore the impact of the intervention on the mechanisms influencing intervention success or failure.



#### *4.6.1. Sampling*

As for the interview sampling methods reported in section 4.2.1., the SLSR was also used to identify patients for this in-depth study. However, for these interviews, I purposefully selected 20 patients in the intervention arm. SLSR data were similarly used to identify patients with particular socio-demographic and risk factor characteristics for inclusion to create maximum variation in characteristics of the group selected.<sup>218</sup> There have been a number of recently published articles outlining challenges and guidance on the conduct of this kind of qualitative process evaluation<sup>115,117,250</sup> and there is debate over the appropriateness of conducting research which interferes with trial process. For this part of the process evaluation, patients were deliberately sampled once they had had their one-year follow-up interview for the SLSR (to collect trial outcome data) so as not to interfere with the main trial (I will return to this discussion in Chapter 10).

Thus the patients included in this part of the study were those who were first recruited to the trial. It is possible that patients recruited later into the trial may have had a slightly different experience since the intervention appeared to become more ‘fine tuned’ as it went along (see Chapter 8). Interviewing those patients who had received a one-year SLSR follow-up also excluded those who could not be traced by the SLSR. These patients are likely to include those less engaged with services and possibly those who have poorer secondary prevention management.

#### *4.6.2. Consent*

Patient and carer consent to participate in the process evaluation was collected at the time of stroke as part of the Stop Stroke Trial. However, many of the patients participating in the trial did not remember that they had agreed to take part in an interview and some did not remember that they had taken part in a trial. For many

patients, research activities since the stroke including the SLSR visits appeared indistinguishable from usual care. Thus prior to the interviews I reminded patients that they had taken part in a research study to test the efficacy of a new package for stroke patients and their doctors. I explained in simple terms what the trial had involved and that I was conducting the interviews to find out what patients thought of the intervention and what actions they had taken as a result of receiving it. Although all interviewees were in the intervention arm, I did not reveal to the patient whether or not they were supposed to have been sent a package (disclosed the trial arm) until they themselves indicated whether or not they had received one.

#### *4.6.3. Data collection and analysis*

To answer the first question (how was the intervention implemented?) copies of all plans sent to patients and professionals were collated with the data collection forms (initial SLSR questionnaires, 3 month and 6 month follow-up questionnaires). Each plan was compared with the original forms to check for errors. The patient and professional plans were also checked against each other for consistency and the content checked for formatting and typographic errors. A list of errors for each patient and each plan was created together with notes on the sources of error.

For the second question (how did the plans influence secondary prevention?) in-depth interviews were conducted with patients and their carers in their own homes. A topic guide was used, based on one developed for investigating secondary prevention management in Chapter 5. This topic guide also incorporated specific questions about the intervention, whether patients had received anything and if so what they had received, their views of the intervention, how they had used it and its impact on stroke secondary prevention (Appendix 6). As in Chapter 5, interviews were audio taped and

transcribed (except for two interviews; one where the patient refused to be taped and one in which the tape recorder failed and detailed field notes were taken instead). Transcripts were then also analysed for emerging themes (see section 4.2.3).

#### **4.7. Summary**

In this chapter I have outlined the methods for the ethnographic study of how the MRC Framework was used in developing and evaluating the Stop Stroke intervention. Different methods were used to investigate specific phases of The Framework including those which are standard within public health such as in-depth interviews and qualitative observational methods and those which are less common within this context such as participant observation. In this chapter I have outlined some of the methodological and ethical challenges arising from using these methods; the implications of these for interpreting findings and enhancing RCTs will be discussed in more detail in the discussion sections presented in each individual chapter and in Chapter 10.



## **Chapter 5. Patients' experiences of secondary prevention**

### **5.1. Introduction**

This chapter presents findings from the first part of the research conducted in the theoretical phase of intervention development to investigate patients' perspectives on secondary prevention. The aim of the theoretical phase was to investigate barriers to and facilitators of secondary prevention in order to design an intervention that would be grounded in research evidence. The research presented in this chapter followed SLSR analyses of patterns of secondary prevention management (outlined in Chapter 1 and presented in Appendix 1) and a review of interventions to improve secondary prevention in vascular chronic diseases.

#### *5.1.1 Optimal secondary prevention*

In the context of health policy for older people and stroke management, secondary prevention can be seen as a specific clinical concept involving the design of strategies to prevent future strokes.<sup>26,27</sup> At the time this research was conducted, recommended guidelines on secondary prevention management such as the RCP recommendations outlined in Chapter 1 were not yet published. More recently, clinical and policy documents have been published outlining strategies to prevent further strokes. These include: monitoring of body processes including blood pressure, cholesterol and body weight to ensure they are kept within clinically defined 'safe limits'; controlling blood sugar levels in people with diabetes; prescribing medications such as antihypertensives or statins to assist in this; and prescribing antithrombotic medications to prevent blood clots from forming. Health professionals are encouraged to provide their patients with

advice on giving up smoking, moderating alcohol consumption, eating a low fat-low salt diet and taking physical exercise.<sup>27</sup>

As discussed in Chapter 1, SLSR analyses prior to the Stop Stroke study and those conducted to inform intervention development, demonstrated inadequacies in secondary prevention management, including low rates of health service follow-up after stroke,<sup>215</sup> under-use of medications post stroke<sup>34</sup> and inadequacies in behavioural risk factor management.<sup>214</sup> Investigation of the relationship between socio-demographic characteristics and management revealed that ethnicity and disability were independently associated with aspects of risk factor control: Black Caribbean and African stroke patients were more likely to have received district nurse support, more likely to be prescribed antihypertensive medication and more likely to quit smoking but were less likely to lose weight if they were obese. Patients with more severe disabilities were less likely be followed up in outpatient clinics, less likely to be prescribed anticoagulant medication but more likely to quit smoking post stroke.<sup>34,214,215</sup> However, these analyses provided little guidance on the best way to improve secondary prevention.

At the time this research was planned (September 1999) there were few published intervention studies specifically targeting stroke secondary prevention (only one intervention was identified and this targeted hospital inpatients with 'teaching brochures' on stroke<sup>148</sup>). Therefore the study team drew on evidence of the success or failure of previous interventions from studies on intervention in primary prevention of stroke disease<sup>152,153,156,158,161,165</sup> and interventions to improve secondary prevention in similar chronic diseases including coronary heart disease.<sup>251-253</sup> Interventions could be divided into three types: those aimed at educating patients about secondary prevention (to improve knowledge or change attitudes or beliefs about secondary prevention); those



targeting professionals, to improve the communication of secondary prevention advice; and those aimed at improving the coordination of care. However, these previous interventions had had limited success in reducing recurrence or improving key risk factor outcomes such as blood pressure control and smoking cessation. Since these interventions were all evaluated using only traditional RCT methods, it was difficult to explain the reason for their success or failure.

#### *5.1.2. Mechanisms for achieving 'optimal' risk management*

While there is no defined 'best way' to achieve public health goals, recent health policy has suggested that personalised healthcare can be used to 'empower' patients to take control of their own health, particularly in relation to chronic disease.<sup>254,255</sup> There is considerable debate over what constitutes personalised or 'patient-centred' care.<sup>256,257</sup> Most models of patient-centred care highlight the importance of patient participation, of sharing decisions about treatment and of attention to the doctor-patient relationship (see Brown, Mead and Bower, Lewin et al., Ong et al. for a full discussion of the components of patient-centred care and their relation to health outcomes).<sup>258-261</sup> Although not clearly defined, the concept of patient-centred care has been described as care 'closely congruent with and responsive to patients' wants, needs and preferences'.<sup>262</sup> Calls for a more patient centred approach have coincided with a shift in the past decade from a traditional 'compliance' model of treatment, in which patients are expected to follow doctors' orders, to a 'concordance' model. Although not necessarily understood or practiced as intended,<sup>263,264</sup> the concordance model implies prescribing based on negotiation and mutual agreement between doctor and patient.<sup>265</sup> It is compatible with a patient-centred approach since it is often assumed that patient-centred consulting is synonymous with patient centred care. The research team



hypothesised that one reason for poor secondary prevention management and a reason why previous interventions had failed may have been the lack of attention to the individual patient experience.

### *5.1.3. Stroke secondary prevention and the patient's experience*

Sociological and psychological studies of prevention have highlighted differences between 'official understandings' of chronic disease and risk management and the lay person's understandings of their illness and prevention,<sup>266-270</sup> hypothesising that many public health interventions often fail because their aims are 'out of step with popular culture'.<sup>267</sup> At the time the research was conducted, little was known about the stroke patient's understanding of secondary prevention but studies of the lived experience of stroke had highlighted the importance of social and cultural factors, such as views about aging, which influence understanding and management of stroke disease.<sup>220,222</sup> Thus the primary aim of this part of the theoretical phase was to identify social, cultural or political influences on 'optimal' management. It was anticipated that investigating patients' experiences of secondary prevention would lead to a clearer conceptual understanding of what secondary prevention means to patients.

An outline of the methods for this chapter is presented in Chapter 4, section 4.2. All extracts presented here and in subsequent chapters are verbatim quotes unless otherwise stated. Patient and carer names have been changed to numbers in the text to protect their identities. Some patients had strong accents or difficulties with speech and the text in square brackets has been added to enhance the understanding of the reader.

## **5.2. Participants**

Participants were 20 people (SLSR patients) aged between 38 and 85 (average age 70 years) all previously diagnosed with acute stroke. Table 9 illustrates the socio-demographic characteristics of those interviewed.

Thirteen patients were women and seven were from Black Caribbean ethnic groups. Six patients were classified as 'independent' in activities of daily living (having a Barthel Index of 20 at three months post stroke) and 14 were moderately disabled (Barthel Index between 10 and 19). However, the ceiling effects in using the Barthel Index as a measure of disability after stroke (particularly for those with mild strokes or living in the community) are well reported.<sup>271,272</sup> Of those considered either independent or only mildly disabled, many described being housebound or were limited in their ability to get out and about and perform household tasks. Fourteen patients were from manual occupational groups although none of these patients were working. All patients were interviewed between one and four years after their stroke.

According to the epidemiological data collected by the stroke register, three patients had controlled all stroke risk factors one-year post stroke, eleven had controlled some of their risk factors (but not others) and two patients had controlled no risk factors.

## **5.3. Factors influencing secondary prevention**

Four key factors emerged as having influenced patients and carers experiences of secondary prevention management. These were health service management of secondary prevention; understanding of the causes of stroke (whether it is preventable), priorities after stroke and the way stroke is conceptualised temporally as an acute event or chronic disease.

**Table 9. Characteristics of interview participants.**

Patient ID	Age	Sex	Ethnic Group*	Socio-economic group* *	Disability***	Stroke subtype	Risk Factors****
1	66	F	BC	M	mod/mild	ischaemic	H, O
2	70	F	BC	M	independent	ischaemic	H, D
3	76	F	W	M	mod/mild	ischaemic	H, A
4	54	F	W	M	mod/mild	ischaemic	D, A, S
5	78	M	W	NM	independent	ischaemic	AF
6	68	F	BC	M	mod/mild	ischaemic	H, D
7	80	M	W	M	mod/mild	ischaemic	H
8	80	M	W	M	independent	ischaemic	H, S
9	76	F	W	NM	mod/mild	ischaemic	D, A
10	61	F	W	M	mod/mild	ischaemic	S
11	80	F	BC	M	independent	ischaemic	H
12	38	F	BC	NM	mod/mild	haemorrhage	H, A, S, O



Patient ID	Age	Sex	Ethnic Group*	Socio-economic group* *	Disability***	Stroke subtype	Risk Factors****
13	58	M	W	M	mod/mild	ischaemic	S, A
14	75	F	W	M	mod/mild	ischaemic	H, D
15	85	F	W	NM	mod/mild	ischaemic	H
16	71	M	W	NM	independent	ischaemic	H
17	74	F	W	M	mod/mild	ischaemic	H, AF
18	69	F	BC	M	mod/mild	ischaemic	H, D
19	64	M	BC	M	mod/mild	ischaemic	AF, H
20	80	M	W	NM	independent	unclassified	A, S

\* Ethnic group: BC Black Caribbean; W White  
 \*\* Social economic group defined using Register General Classification NM non manual groups (I, II, III non manual) and M manual groups (III manual, IV, V)<sup>273</sup>  
 \*\*\* Disability defined using the Barthel Index: independent (total score=20); moderate/mild (total score 10<20); severe (total score<10)  
 \*\*\*\* Risk factor abbreviations: H hypertension; D diabetes; AF atrial fibrillation; S smoking; A heavy alcohol use;<sup>34,214</sup>

### *5.3.1. Health service management*

From patients' accounts three categories of health service management of secondary prevention emerged: opportunistic management, organised management and lay management.

#### *5.3.1.1. Opportunistic management*

When questioned about health service monitoring of risk factors and delivery of secondary prevention, the picture described by most patients was a haphazard or 'opportunistic' approach. For example, some patients described having their blood pressure checked if they happened to visit their GP but also explained that they did not routinely see their GP.

JR: And do they [the doctors] ever check your blood pressure?

Patient 3's husband: They do when you go round, although you ain't been round there lately but when you go round there, yes.

Alternatively, others described seeing their doctors frequently but did not necessarily get their risk factors monitored when they were seen:

JR: Does he [the patient] ever get his blood pressure checked?

Daughter 7: When you go into the hospital you get your blood pressure checked don't you?

Patient 7's wife: He hasn't had it done for ages.

Patient 7: I've had a lot of blood checks.

Patient 7's daughter: No blood pressure?

Patient 7: Not that I know of.

Patient 7's daughter: Not when you go to the doctor you know the machine that they wrap round your arm?

Patient 7: No.

In some interviews it was difficult to identify just how often the patient actually saw their GP or other health professionals. Definitions of what 'regular' meant in relation to

having regular check-ups were diverse. For some, seeing the doctor every few months was thought to be 'regular', for others a fortnightly check-up was infrequent. Patients might go to the GP surgery on a frequent basis but it was not clear whether such check-ups included secondary prevention.

JR: Do they check your blood pressure regularly?

Patient 6: Not regularly, no.

JR: And how often do you go to your doctor, is this your GP?

Patient 6: Yes my GP, haven't been to him very often. I went there 2 weeks ago for this flu jab. So I haven't seen him now for a while, he came once.

Patients on repeat prescriptions collected their medication without seeing a professional. These automated systems for making appointments and collecting prescriptions may have facilitated access to medication for some patients but at the same time appeared to act as a barrier to accessing clinical advice. The organisation of GP care may have prevented patients from accessing advice on secondary prevention since it would have meant making a specific appointment to do so. Patients appeared to see the GP as someone who was responsible for them when they were sick and having had a stroke in the past did not necessarily constitute being currently sick. One patient had not seen his GP for over three years since the stroke. He explained that he only visited the GP if he thought there was something seriously wrong with him.

Oh yeah I mean if I really felt ill of course I'd go down and see him. Like the eye when I realised it wasn't opening like it should have done, I thought there was something wrong with it, you know, that's when I went down. (Patient 20)

Some patients described their GPs as being 'too busy' and they would not make an appointment unless they had an emergency (they were sick) or needed a specific procedure such as a flu injection. Practically, seeing the doctor appeared to be discouraged:



JR: So do you go to your GP regularly?

Patient 7's wife: No

Patient: Only to get my prescriptions and that and then I only see the receptionists. I don't get to see the doctor

Patient 7's wife: He doesn't ask, you have to ask to see the doctor, which is very hard to do.

JR: Why is that?

Patient 7's wife: They put you off...

Patient 7: When you go over there you're sitting there for hours before you see the doctor. You can even make an appointment time but it makes no difference its still 2 or 3 hours before you go and see a doctor. That's what puts me off. But then if you imagine you can make an appointment for the afternoon and it might take about a month before you get that appointment. That's what puts me off.

#### *5.3.1.2. Organised secondary prevention*

However, despite the overwhelming sense that health service organisation of secondary prevention was haphazard, some patients did describe seeing hospital or GP services on a frequent basis. These patients were categorised as having organised secondary prevention management. Patients in this category had been provided with advice about ways to help prevent further strokes and had routine monitoring of risk markers such as blood pressure or diabetes.

JR: You said you go to a doctor quite a lot. How often do you go to your doctor?

Patient 2: About twice a week, check the blood pressure and check the diabetic [sic]. I see the doctor very often and check the blood pressure very often and the diabetic [sic] very often.

However, not all patients in this category were receiving their care specifically in relation to their stroke. Some patients were receiving regular monitoring of risk factors as part of their care for a concurrent disease and organised through another specialty (such as cardiology or diabetes care). In fact it was almost as if the only people who

received ongoing organised management were those who had this organised through a separate specialty. There appeared to be no specific specialised ongoing follow-up for stroke. One patient did state that he had attended the stroke clinic on a regular basis but it was difficult to tell whether the focus of these visits was on stroke recovery or whether it was to check up on his smoking and alcohol use. Certainly from the patient's point of view these visits were not about helping him to prevent future strokes.

JR: And have you been back to the hospital at all?

Patient 12: Oh yes, I go back every month, I go back and the last time I went they said I got to go back every 3 months.

JR: And is that to see people about your stroke or is that...?

Patient 12: [interrupts] Awful, they don't do nothing.

[later in the interview]

JR: And when you actually get to see the doctor what happens?

Patient 12: give up drink and smoking they say...They've got a great job them doctors, sitting down there, two of them.... They do nothing.

Since the patient's understanding of stroke focused on physical symptoms and the residual disability resulting from the stroke, services that focused on secondary prevention issues even if delivered in a specialist environment, were not seen as stroke specific by the patient.

#### *5.3.1.3. Lay management*

Stroke specific services appeared to be short lived, being restricted to hospital rather than community services. Some patients were angry, feeling that their stroke monitoring had been terminated before their stroke problems had been resolved.

I'm very bitter [with named hospital], they just don't care, there's no care in society, care in society has just gone out the window. They stitch you up put you on a train and send you home and that's it. Nobody...you don't get after care. (Patient 9)

Without organised stroke follow-up and given the haphazard nature of routine monitoring, some patients appeared to rely heavily on 'lay support' from friends and relatives to assist them in their secondary prevention management.

When she first came home she refused to take her medicine her tablets so I can't remember whether I did or not, anyway we must have gone over and told the doctor she wasn't taking them. So she sent a district nurse from the [named] centre, [named] estate. Do you know the [named] estate up there in [named town] they've got a big sort of health centre. She [the nurse] came here and she said she [the patient] must take them. And it was her and the doctor said that she must take them...I thought she [the nurse] was gonna come back and see that she took them but she only ever came the once she never came no more. But anyway, we got round to making her take them and she's taken them ever since....she takes them alright now. Mind you you've gotta be after her. Because you know my brother leaves them there he puts them in the cup, 2 in the little egg cup for her morning ones. And then half way through the morning he says to her you haven't taken your tablets. She says yes I have he says you haven't they're still here, oh alright! You would think she'd help to look after herself. If we weren't here I dare say she would be up the wall. (Patient 7's sister)

This haphazard approach to routine secondary prevention delivery appeared to influence not only the delivery of secondary prevention monitoring but also the uptake of health promotion messages. Some patients could recall being given advice in hospital or by their GP (such as stroke education, information leaflets or an opportunity to ask questions of a health professional) that satisfied them at the time but on leaving hospital the advice could not always be recalled, perhaps due to the time of delivery. Ley's model of behaviour change demonstrates the importance of information recall in influencing health behaviour.<sup>274</sup> Shortly after the stroke, patients and their carers may have been more concerned with recovery and getting home than on secondary prevention. In one interview the discussion turned to provision of written information. The patient and her daughter described how they had not been given any written advice



on stroke management and had had to seek it out themselves. However, later on, the patient said that she had read something about stroke in a leaflet in hospital. The daughter described how the nurses in the hospital had informed her about the stroke and given her the opportunity to ask questions but at the time she had not been that interested

Well I've got to be honest, the nurses when she was in [named hospital], on the ward she was in, we weren't bothered because we was really worried, we nearly lost it. (Patient 4's daughter)

She went on to explain how the nurses had taken her aside into a private room and spent about half an hour with her answering her questions. Unfortunately as she put it 'but that was in hospital' and on returning home she and her mother had been forced to rely on their own initiative.

JR: And what about information since you left hospital?

Patient 4's daughter: We've done it yourself really, we've done it ourselves

Once in the community, some patients felt that the information they had received was not relevant.

JR: Have you ever had any written information about your stroke like this [JR shows the patient a selection of leaflets]?

Patient 11: I got one at the hospital...

JR: And did you find it useful?

Patient 11: Not really, it's mostly for older people. It was a shock to me. I didn't know that a young person could have a stroke.

There appeared to be little opportunity for secondary prevention messages to be reinforced once patients had been discharged from hospital. It was difficult to ascertain whether the low levels of information provision reported in stroke studies<sup>275-277</sup> were because secondary prevention advice had not been provided or whether it was simply not salient. When questioned about secondary prevention advice and information, many

patients referred to information they had received about other aspects of their stroke rather than about secondary prevention.

However, even when patients did recall receiving secondary prevention advice post stroke (from information leaflets or their GP), some patients' interpretations of the advice appeared at odds with current secondary prevention recommendations, suggesting that there was no mechanism to ensure that secondary prevention messages were understood. One patient described his interpretation of his GP's dietary recommendations:

Patient 8: ...the doctor, the GP give me some of those [information leaflets], to help with eating and doing your food and whether you want fish or drink anything, vinegar or anything like. Oh give you advice about what is good for you. Oh they're very good over there

JR: So did you find the leaflets quite useful?

Patient 8: Well I did and I didn't actually. Because I don't go crazy like with certain food I just do a normal, like chips or something. I don't have any of that fancy stuff. I thought if I did want any of the fancy stuff I wouldn't be able to eat it. No it's been good advice like the drinking and sort of thing. If you want a beer or something that's OK provided you don't go crazy with spirits. Which he did tell me once – he said do you drink spirits? I says no, a weak beer. He says no beer's all right. You can have 2-3 of them, no problems.

Although he had been informed of the need to eat a healthy diet, his interpretation of healthy food appears to be food that is 'not fussy' rather than foods low in fat and salt as described in health promotion and stroke literature.<sup>27,278</sup>

### *5.3.2. Beliefs about stroke and models of prevention.*

Perhaps because of the way stroke is conceptualised and the way services are organised (more as an acute event than a chronic disease), it was not easy to engage patients in discussion about preventive action for the future. When initially contacted about the

study, a number of patients had commented that it was too late to be talking to them about stroke prevention. There appeared to them, to be little relevance in focusing on preventive strategies if the stroke had already happened and was now something of the past. Given the lack of information provision described by patients, they may have been unaware that they could have subsequent strokes. However, lack of knowledge could not explain the lack of concern expressed by some patients, since they had been explicitly told by health professionals that they could have more acute events in the future.

JR: You said that the doctor said to you that you could have another stroke. Do you worry about that?

Patient 8: Well you do to a certain extent but I think to myself well I don't know. If you've already had the stroke you've just got to you know [make the best of it]. But I've been lucky and touch wood, I haven't had the [problems with] movements [disability]. I mean I've seen people in the markets there – young people you know. Really they're in a position where they [should] be going to a church, you know.

It is often assumed in the literature that risk management will be more relevant to those who already have a disease than to the general population,<sup>28,29</sup> since it is hypothesised that those who have already experienced the symptoms of an illness and are thought to be at high risk, will be more fearful of the future. This hypothesis did appear to be partially supported in the interviews since some patients talked of the fear they experienced in relation to their acute event.

It is frightening when suddenly it comes and for two days it don't feel at night, I couldn't sleep. It hurt, it hurt (until somebody gave me something)...but I really suffering [sic], especially the stairs up till now. I don't recover that still yet. Still have a problem with the stairs - can't get to my room you know, the balance, I stay down here – you should see the way I walk, because I'm scared I'm down here. It is bad. (Patient 6)



However, fear surrounding the acute event did not necessarily translate into worry about preventing strokes in the future. Fear for the future appeared to be heightened immediately after the acute event. A year on, patients learned to focus on other things. While this may not have been helpful for secondary prevention management, it may have been a coping strategy to consider the stroke as something in the past.<sup>266</sup>

Well, it got to the stage, after having one, I used to wake up in the morning, I used to worry. I keep trying to quote my old army number, 23.9829 and if I could do that, I knew I was all right. You know, when you first woke up, 23.9829, oh yeah, that's all right. But apart from that, no, it's not a problem, I don't even think about it now one way or another. I keep myself busy out in the garden. (Patient 5)

Psychological theories have highlighted the importance of beliefs or representations of illness in influencing illness behaviours<sup>200,279-282</sup> and it had been in the original proposal for the study to investigate patients' beliefs about stroke causation and prevention. It was anticipated that where risk factors were well managed, patients would have a clearer understanding of stroke aetiology as defined in epidemiological and clinical studies.

In the interviews there did appear to be a relationship between patients' understandings of prevention and their interpretations of what had caused their initial acute event. Some patients explained that there was little they could do in trying to prevent a future stroke since strokes were random events that could not be prevented. For others, the stroke simply could not yet be explained scientifically and current secondary prevention strategies were not perceived as being advanced enough to make a difference

Patient 7's daughter: I tried to talk to the doctor that was standing in there and she more or less said well you can't really do much about it. So I said what the hell are we doing here?

JR: Did she not explain it?

Patient 7's daughter: Not really I got the impression she could say a lot of things but it wouldn't really make much difference. It's just a question of he'd continue to have mild

strokes. Each time he had one it would get a bit worse, he wouldn't recover every time as much...that's just about it.

JR: But she didn't explain anything to you about what you could do to help stop this happening?

Patient 7's daughter: No I got the impression you couldn't do anything. That's the impression I got....Wait till they get these gene things sorted out because when they can pinpoint which genes do this that and the other it'll solve all the problems. It's just a question of waiting. Perhaps when it's my time you'll just be able to take a tablet and probably when you're my age you probably won't have any of these problems at all.

Those who did think there was something that could be done described different models of prevention. Three models emerged. Firstly, a medical model in line with public health theory on secondary prevention, where modifying risk factors could prevent a stroke

JR: Do you think the medication that you're taking could stop you having another stroke?

Patient 4: I hope so that why I take it. Aspirin, I definitely worry about taking it.

Secondly, a stress model in which patients suggested that stress or anxiety had contributed to the stroke and so taking it easy or removing that stress would prevent a recurrence. Some patients discussed a particularly stressful event which they thought had triggered the stroke including death of a spouse, problems at work or problems with housing, while others talked more generally about the problems of stressful lives, building up and contributing to poor health over time.

JR: Do you think anything like smoking, or diet, or alcohol, are related to strokes?

Patient 5: Well, I, I mean, anything you take to excess, you're asking for trouble, ain't you? If you do it in moderation, I can't see any...I think one of the worst things is blood pressure and stress, I think, especially, today, I mean it's all bloody stress, everybody's fighting for their job, or fighting to be a bit better than the next one and all that. I think that's the main cause of it, as I say, it's better to be doing, to be one notch under what you're capable of, than one notch above it, cos one notch above you're in trouble.



Thirdly, a spiritual model was described where patients felt that God had caused their stroke and so praying would help prevent further strokes. However, alternative models of prevention such as stress or spiritual beliefs did not necessarily translate to fatalistic views about the future (see Davison et al. for a discussion of the limitations of psychological theories of illness attribution<sup>283</sup>) since these models were not mutually exclusive. Patients could at the same time believe it was important to control blood pressure (medical model) and reduce stress (stress model). Holding a spiritual model would not necessarily negate the need to take medicine to prevent further strokes, the two models might even complement each other.

Well I pray over my medicine. Because the doctor can give you medicine but it is God that do the healing. We pray over our...just as you pray over your food that is the same that you pray over your medicine and God will remove the side effect. You see some people just take medicine and drink it but I pray over the medicine. (Patient 1)

What was not clear from questioning patients about their understanding of stroke causation and preventability of future stroke was the extent to which these models actually influenced the patient's behaviour. When questioned about the importance of engaging in specific preventive behaviours, patients talked more about their priorities, than their understanding of stroke causation.

### *5.3.3. Priorities after the stroke*

Previous studies have highlighted the importance of individual context in influencing lay understanding of prevention.<sup>267</sup> This is perhaps particularly relevant in the context of stroke, which affects mainly older people and can lead to long-term physical or psychological difficulties. In this study, patients talked about clinical secondary prevention strategies in terms of their priorities, using a type of economic cost-benefit approach.<sup>267</sup> The benefits of managing risk factors appeared to be weighed up against



the costs of having to engage in risk controlling behaviours (giving up smoking, cutting down on alcohol, losing weight or taking tablets).

Whether these models were used to inform cognitive decisions about risk management or whether patients presented them in interviews as an afterthought, to justify why they were/were not engaging in specific secondary prevention activities, was not clear. However, in some cases the stroke appeared to have had a significant impact on the patient's ability to fulfil social roles or participate in activities. Specific risk factor behaviours such as smoking or drinking were some of the few pleasurable distractions patients had left as illustrated by one young woman's experience. She had a stroke at the age of 34 and now four years on described still being restricted in leaving the house due to problems with incontinence since the stroke. In such cases decisions not to engage in risk factor control appeared quite rational.

JR: And you said they told you to cut down on drinking as well, do you drink a lot?

Patient 11: yes, too much

JR: And did you try to cut down on that?

Patient 11: Yes, I seem to have got worse over the years. Because there's nothing for you to do, you get bored and the only source of comfort is drinking booze and cigarettes, it's a bad cycle.

Yet while it may have been helpful for patients to prioritise health promoting behaviours specifically for the purpose of stroke prevention, it was not a necessity for patients to see a direct cause and effect relationship. Some patients felt that behaviours (such as exercise) that might help prevent future strokes were important, not because they could prevent a further stroke but because they brought general health benefits.

Well to me I feel exercise makes you became more fitter. But I don't think the exercise, you understand me, if you haven't got the stroke, you take your exercise, your body feel more fitter. But I don't think, if you've got a stroke, don't matter what exercise you take and no matter what you do, you're still going to have it. (Patient 19)

Equally for some, engaging in risk controlling behaviours appeared to be more of a routine, or a reaction to medical advice, than the result of decisions about preventing stroke. Some patients suggested that they were happy to engage in secondary prevention behaviours (such as tablet taking) without any understanding of the aims of doing so.

I take it because that is what they gave me at the hospital. I don't know what it is doing.

(Patient 14)

#### *5.3.4. Health and social factors influencing priorities*

Patients' priorities after stroke and their ability to engage in secondary prevention appeared to be heavily influenced by their health and social circumstances, either as a result of the stroke or from a pre-existing problem. Approximately one third of stroke survivors are estimated to experience some form of residual physical or cognitive disability after stroke<sup>25</sup> and this appeared to have an important influence on secondary prevention management. Cognitive problems influenced medication use, since some patients who were happy to take their medication had difficulty remembering it. The husband of one patient described how his wife's cognitive problems made her dependent on him for aspects of secondary prevention management. At the start of the interview he had told me that his wife had problems remembering things that had happened since the stroke. This was not obviously apparent at the start of the interview but after about half an hour she started to repeat things she had discussed earlier. It became clear that without her husband's assistance the patient would not have remembered to take her medication.

Interviewer: Did they put you on any medication or anything when you came out [of hospital]?

Patient 3's husband: Well, she's got loads of medication actually but, you know....these blood pressure pills and aspirin I should think...I know that you were put on aspirin.

JR: And, and how often do you have to take them?

Patient 3's husband: Daily.

Patient 3: What do I do with those aspirins, two a day, three a day?

Patient 3's husband: Daily, two, two a day, two a day.

Patient 3: Yeah, you lay 'em out on the table don't you?

Patient 3's husband: Yeah, otherwise if I don't get it, get them, she won't bother, if you know what I mean.

JR: And do you, do you have any problems at all about taking them or do you not mind taking them?

Patient 3: No

Patient 3's husband: Provided I put 'em there she'll take 'em and if I don't put 'em there she won't.

Physical problems also appeared to act as a barrier to secondary prevention even if secondary prevention was seen as a priority. Some patients, despite being aware that exercise was important for their health, had stopped taking exercise since the stroke because they felt fatigued or were physically unable to be active, making them reliant on family or friends to collect their prescriptions or to help them get out and about.

JR: And do you ever get out at all?

Patient 10: Not unless my daughter, I couldn't climb the stairs, I had to have a shower put in because I couldn't get in the bath.

JR: And was that after the stroke?

Patient 10: Yes...I don't go out because I can't walk anyway and my daughter does everything for me.

Social, environmental and economic limitations were also discussed in relation to risk factor management. Some patients talked of the financial difficulties they experienced and while financial constraints might have assisted in some aspects of secondary prevention management (one patient talked about cutting down on smoking and alcohol to save money), having financial difficulties also appeared to prevent patients from



accessing services. None of the patients interviewed had access to a car for getting to and from hospital or their GP surgery and some patients talked of the difficulty they had in walking to their local surgery and getting to hospital or using public transport.

I don't do much walking because you know, because I is scared of falling. I don't go out any more. (Patient 14)

Some patients stated that they were afraid to go out alone in the local neighbourhood. This might, as Bandura suggested, be due to lack of self-efficacy (or self confidence) in going out alone.<sup>279</sup> However, many patients talked of practical difficulties negotiating the environment since the stroke. Patient 4 described how her shoes fell off while she was walking because she could no longer bend her foot and was unable to bend down and put them back on. Others talked of difficulty going up and down steps or problems negotiating traffic.

JR: And would you if you had any questions be able to ask your GP?

Patient 13: I couldn't go there on my own.

JR: Is your doctors quite a long way away?

Patient 13: You've got to cross too many roads.

JR: And you couldn't use public transport?

Patient 13: No.

Others still, described their local area as being too dangerous and felt that since the stroke they had become vulnerable to being mugged or attacked (their local Boroughs falling into some of the most deprived boroughs in England).<sup>284</sup>

#### *5.3.5. Stroke as an acute event or chronic disease*

The clinical concern for management of risk factors to prevent recurrence implies construction of stroke as a chronic condition. By contrast patients described their stroke largely in relation to the acute event. At the start of each interview participants were first asked to talk a bit about the stroke and to describe what had happened to them.

Almost without exception, this question initiated a history of events focusing on the acute stroke experience, including descriptions of what patients had been doing at the time, who they were with and whether they had contacted their doctor or called an ambulance. The symptoms they had experienced during the acute onset were particularly vivid in patients' descriptions, such as loss of consciousness, weakness in their limbs and problems with speech or coordination.

I just went to bed normal, I wasn't reading. I mean I might go to bed at ten o'clock some nights, half past ten. But I read until about twelve o'clock, half past twelve, in bed like, I like reading. And I just woke up, me eyes was closed, this one was closed, just closed, you know, no pain with it. I looked in the mirror like and I thought, you know, it seemed as though it was stuck, you know, when you over sleep sometimes like. Anyway it never went away after three or four days and I rang up the GP and he turned round and said, "Oh I think you've had a slight stroke". (Patient 20)

Thus, from the outset, it appeared that 'the stroke' referred specifically to the acute event itself, the symptoms relating to it and the events that happened, rather than to any pre-existing health concerns or underlying unseen bodily damage.

Lawton has discussed the importance of 'embodiment' in relation to cardiovascular prevention, suggesting that those who experienced symptoms of cardiovascular disease would be more likely to seek out and relate to strategies for prevention.<sup>239</sup> In these interviews, experience of stroke and subsequent residual disability appeared to play similar roles in helping patients to understand their illness. If patients still experienced symptoms and saw themselves as still recovering or improving, then this helped in conceptualising the stroke as an ongoing disease. However, if patients did not experience symptoms, or could no longer see any change in their symptoms or disability, then the stroke was viewed as a thing of the past:

JR: So, so do you feel like you've recovered from your stroke now, do you feel like it's, you're, you're over it?



Patient 3: [it's a couple of years now] init, a couple of years.

Patient 3's husband: Well it's over and done now I suppose.

Patient 3: Once you, once you feel alright, you pull yourself round, you don't harbour on it, you forget it don't [you], you try to push it away

However, while symptoms were clearly influential in shaping patients' understandings of the stroke, their experiences also appeared to be linked to ongoing monitoring of risk factors. Even if the symptoms had disappeared, the stroke could still be seen as a current health problem if continuously monitored by health services.

JR: Do you feel now then, that you've recovered from your stroke, completely, or...?

Patient 4: I've got, I've always been careful, well, you know, I do really, yeah. 'Cos I know I can keep on with what I'm doing, you know, the tablets get checked every three months and the blood six and oh yeah, I've got every confidence in them, ...the treatment I'm getting, is bloody marvellous, you know.

Although in the above example the patient described receiving ongoing monitoring, this was not the pattern of service provision described by most of those interviewed. Instead, organisation of stroke services focused mostly on the acute event with few patients describing any ongoing stroke monitoring in the months or years following the stroke. Patients did not necessarily view the sort of care that the research team had considered to be part of secondary prevention management (diabetes management, hypertension monitoring, attendance at warfarin clinics) as being related to the stroke. For example, in some cases patients described seeing health professionals for risk factor management prior to the stroke (visiting the diabetes clinic or cardiologist) and so continuation of these practices was not viewed as being part of stroke care. Since most patients appeared to relate the stroke to specific physical or psychological symptoms it was only the services that targeted these symptoms (such as physiotherapy) that were seen as being stroke specific services and in some cases patients were unaware that the risk factor monitoring they received was related to their stroke.



JR: So it's just the people at the Warfarin clinic that see you?

Patient 17's sister: Yes that's the only people and all we do is you go over there you go in, you put your card in, being a wheelchair patients she's one of the first to be seen too. They prick her finger on a bit of thing shove it in the machine. He tells her whether it was all right or not and you come out – everybody does this. And you go up to another room and whether he's a doctor or what he is he tells you, you know, that it was alright or what and gives you your next appointment and tells you he'll see you again in 6 weeks time. And then you're out. You're in and out in well not long so... Well no one sees her about the stroke.

Thus while stroke is conceptualised within epidemiology as a chronic disease, this is not necessarily the case for those experiencing the stroke. While health service management may have the potential to influence the patient's embodied experience, current health service management does not encourage this view.

#### **5.4. Discussion**

This study used in-depth qualitative interviews to explore the experiences and understanding of patients and their carers in order to identify factors influencing secondary prevention management. In particular it aimed to identify barriers to secondary prevention that could be targeted by the new intervention to improve management.

From the outset, it became clear that achieving 'optimal' management was a complex process involving many different individual, social and environmental factors. Patients were often required to manage multiple risk factors involving taking both pharmaceutical therapies and modifying a range of behaviours. Having one risk factor controlled was not necessarily an indication that all risk factors would be well managed and assumptions that patients could be neatly classified into those with optimal or sub-optimal management were misplaced. Whether or not a patient's risk factors were

controlled appeared to be influenced by an interaction between health service input (specialist stroke services, attendance at primary care or community services for other concurrent health problems); social support; individual understanding of stroke disease and prevention; and a range of other physical, cognitive, economic and psychosocial factors including individual priorities following stroke.

#### *5.4.1. Organisation of services*

Evidence from these interviews suggests that stroke services are organised around the acute event, focusing primarily on the physical aspects of stroke recovery and being available for a limited time period only. From examining patients' experiences, ongoing organised stroke secondary prevention did not appear to exist and risk factor surveillance was limited to other disease groups such as heart disease or diabetes. Most other secondary prevention monitoring appeared to occur through opportunistic health service contacts. Patients might receive monitoring if they happened to contact their GP but there was no automatic mechanism for recalling patients to guarantee either that patients would routinely visit their GP, or that visiting the surgery would lead to secondary prevention monitoring. The organisation of appointments and management of medication using repeat prescription may have created the perception that seeing a doctor was for emergencies only and discouraged patients from contacting busy health professionals specifically to discuss secondary prevention. Where patients did not receive ongoing monitoring through concurrent disease management, there was no alternative and patients were dependent on existing social support networks for ongoing management.



#### *5.4.2. Knowledge, education and beliefs about secondary prevention*

Knowledge or education is often thought to be a prerequisite for adherence to health promoting behaviours or medication<sup>274</sup> and is a feature of many previous interventions targeting cardiovascular disease secondary prevention.<sup>251,252</sup> This perhaps stems from the assumption that sub-optimal secondary prevention management is the result of patients' erroneous or irrational beliefs about health and illness and that education can be used to manipulate these beliefs in order to improve health behaviour outcomes (see Sheeran and Abraham<sup>285</sup> on the origins of the Health Belief Model and other cognitive theories of illness behaviour). However, in this study there appeared to be no clear association between knowledge of secondary prevention practices or health beliefs and secondary prevention management. A recent qualitative study into patients' causal attributions after myocardial infarction concluded that patients may have multiple models of illness causation and that certain (perceived to be inappropriate) beliefs about causation (such as bad luck) were not necessarily the result of lack of knowledge but a coping mechanism for justifying responsibility after the event.<sup>266</sup> In this study some patients appeared to be able to achieve 'optimal' management without any knowledge of stroke or stroke prevention. Whilst it could be argued that knowledge probably is a prerequisite for making educated decisions about secondary prevention management, there should be no expectation that an increase in stroke knowledge would necessarily lead to improvements in risk management outcomes.

The models of stroke causation and prevention identified in this study appeared to be used by patients to explain what had happened and, in some cases, in discussing health behaviour choices for preventing future strokes. However, it was not clear whether these models were used to inform health behaviour choices prior to engaging in health behaviours, whether they had been constructed after the event to explain current



preferences for risk management, or whether the models were voiced simply for the benefit of the interview.

#### *5.4.3. The individual context, prioritising secondary prevention*

As Davison et al. suggest, in order to understand the reasons for successful or unsuccessful risk factor management, it is necessary to understand how decisions to engage in health promoting behaviours are rationalised and prioritised according to the individual context of the patient.<sup>267</sup> These interviews demonstrate how failure to engage in a particular stroke secondary prevention practice, such as visiting the doctor for a blood pressure check appears almost inevitable if a person has problems with mobility and is unable to leave the house alone. Such decisions are not necessarily due to lacking in self efficacy as many psychological models suggest,<sup>279</sup> but might be due to physical disability or practical difficulties getting out and about. Likewise a decision to prioritise smoking over stroke prevention might appear quite rational if the person is no longer able to participate in social activities they previously enjoyed prior to the stroke. Physical and cognitive ability, social support, social and environmental circumstances may be particularly important in influencing patients' priorities in the case of stroke where such a high proportion of patients experience some form of residual disability. It is perhaps not surprising then that education or coordination interventions alone have had limited influence on improving risk factor management.

#### *5.4.4. Summary*

In the introduction for this chapter, I discussed previous attempts to improve risk factor management in coronary heart disease and stroke, focusing on patient education, service coordination and training of health professionals. The limitations of these particular

interventions cannot be explained by this study but these interviews do suggest that while education, coordination and training are all likely to be important in risk factor management, secondary prevention cannot be taken out of context of the stroke experience as a whole. Novel ways need to be found to overcome the physical, cognitive and social difficulties commonly experienced by patients after stroke. For example, retraining hospital specialists to attend to patients' information needs in hospital is unlikely to have an impact if secondary prevention is not a priority for the patient or their carers during the hospital episode. Introducing a nurse coordinator to improve patient access to services is unlikely to have an impact if current services are designed around the acute event rather than chronic disease management. While patients may appreciate and benefit from more structured secondary prevention education after stroke, it should not be assumed that making educated choices and making choices compatible with current public health goals are necessarily one and the same.

The research for this part of the theoretical phase may not be able to address all the gaps in our understanding of secondary prevention practice but it does provide some explanation of the multiple social, psychological and cultural processes influencing patients' experiences of secondary prevention management. Any intervention based on these findings would need to consider these in its design and evaluation.

## **Chapter 6. Secondary prevention in the stroke clinic**

This chapter presents further findings from the research to inform intervention development. The research used qualitative observational methods to investigate the delivery of secondary prevention strategies by healthcare professionals in the stroke outpatient clinic.

### **6.1. Introduction**

As we have seen, previous studies of interventions to improve secondary prevention targeting multiple risk factors have hypothesised that poor management was either the result of poor communication by health professionals or poor coordination of care.<sup>251,252</sup> Members of the research team (and in particular the lead stroke clinician) felt that communication style was likely to be particularly important in explaining poor secondary prevention management. Roter et al. have conducted considerable research aimed at identifying and measuring attributes of particular communication ‘styles’ that promote patient adherence.<sup>286,287</sup> Yet, while there is some evidence that particular attributes are associated with patient satisfaction and even patient recall, there is little evidence to support the hypothesis that communication style influences other outcomes such as adherence to medication and clinical advice, or subjective measures of health outcome.<sup>261</sup> Thus, this investigation was not limited solely to exploring communication style.

In this chapter I draw on two theoretical frameworks to understand delivery of secondary prevention in the stroke clinics: (i) current theories of the social context of risk were explored to understand how professionals practise risk construction and represent risk to patients: (ii) the concept of a patient-centred approach to care (outlined



in Chapter 5) was used to understand organisational barriers to achieving public health goals for ‘optimal’ risk management in the stroke clinic. A brief discussion of these concepts and how they relate to stroke risk management is presented below.

#### *6.1.1. The social context of risk*

Social scientists have theorised the notion of ‘risk management’ in a number of different ways, including risk management as a tool for controlling future uncertainty;<sup>288,289</sup> as a means of categorising individuals into social groups;<sup>290</sup> for allocating responsibility and apportioning blame;<sup>269,291</sup> and as a mechanism for surveillance and socio-political control.<sup>292</sup> Although there have been numerous studies focusing on risk management in chronic disease (see Lupton, for an overview),<sup>269</sup> to date, the literature has tended to focus on investigating the notion of risk in people without disease and how these representations are used to manage particular categories of people. For example the HIV literature has demonstrated how risk has been used to control already marginalized groups such as homosexuals and drug users.<sup>293</sup> Little is known about the significance of the risk concept amongst those for whom the risks have already been realised, that is, people with disease.

In Chapter 5, I demonstrated how individual patient and social factors including individual priorities and service organisation, influenced patients’ understandings of risk management and the activities they engaged in after stroke. Other studies of stroke survivors’ experiences have suggested that understanding of stroke and stroke management are shaped by cultural, social and political structures.<sup>220-222,294</sup> In this chapter I focus on social and political influences on *professionals’* practice in relation to management of risk after stroke. Little is known about how professionals understand and manage risk in this context, although the complexities of constructing medical

knowledge have long been recognised.<sup>295,296</sup> For example Jackson et al. emphasise the non-rational and subjective ways in which professionals use evidence-based medicine in managing cardiac risk, with trust in specialist knowledge and personal experience in some cases overriding ‘evidence based’ risk reduction recommendations.<sup>295</sup>

In the context of secondary prevention management ‘risk’ refers both to risk factors (characteristics of the individual patient’s body or behaviour making them ‘at-risk’) and the probability of having a subsequent stroke. Strategies to prevent further strokes (such as those outlined in the previous chapter) can be seen as strategies to manage risk.

#### *6.1.2. Organisational influences on ‘optimal’ risk management*

I have already outlined a definition of ‘optimal’ risk management in Chapter 5. One of the findings from the SLSR analysis presented in Appendix 1 was that a substantial proportion of patients do not receive adequate health service follow-up after stroke.<sup>215</sup>

Follow-up was significantly associated with provision of certain risk controlling strategies such as medication prescribing. However, as the findings from Chapter 5 suggest, even when patients do access health services, secondary prevention issues are not always addressed. These findings illustrated how health service organisation influenced both patients’ understandings of secondary prevention and access to appropriate management strategies.

Other studies of stroke survivors’ experiences of stroke have also demonstrated the importance of ‘system’ influences on patients’ experiences of stroke for example in relation to stroke recovery. Hart illustrated how problems within a health system, particularly interactions with health and social services at transitional time points, may lead to ‘setbacks’ for patients which consequently have a negative impact on recovery.<sup>81,297</sup> The primary aim of this part of the theoretical phase was to identify



social, cultural or political influences (facilitators and barriers) on delivering optimal secondary prevention management in the stroke clinic.

An outline of the observational methods used to collect and analyse data is presented in Chapter 4 (section 4.3). Extracts presented have been selected to illustrate the emerging themes and are verbatim quotes unless otherwise stated. Each quotation or extract is identified by the clinic number (Clinic 1 or 2) and the consultation number.

## **6.2. Clinics and Participants**

The study participants included two hospital specialists, a consultant physician and a consultant neurologist both with an interest in stroke medicine, four specialist registrars and one specialist stroke nurse. Both clinics focused on stroke disease but neither was dedicated specifically to providing secondary prevention, each consultation also covering a range of clinical, psychological and social topics related to stroke.

At Clinic 1, the consultant (C1) saw most of the patients himself, although, if the clinic was busy he was assisted by a specialist registrar (trainee who was not observed). Consultations with 35 patients (eight women) aged between 45 and 92 were observed during the study period at clinic one. Most attended for a follow-up consultation after a period of treatment in hospital or a previous outpatient clinic visit. Seven were newly referred (by a GP or other hospital professional). Consultations focused largely on stroke recovery, providing an opportunity for the doctors to monitor patient progress since the stroke.

At Clinic 2, the consultant (C2) was assisted by a team of trainee doctors and a specialist stroke nurse. Each week at least one of the trainee doctors conducted blood tests for research purposes alongside the stroke clinic but was not involved in providing clinical care. All newly referred patients were seen by one of the trainee doctors to gain



experience in diagnosing stroke. The trainees reported back to the consultant, who, in almost all consultations had a brief consultation with the patient before final clinical decisions were made. Most patients returning for a follow-up appointment, were seen by the consultant alone. Trainees alternated over the study period: junior doctor one (JD1) left the team and was replaced with junior doctor five (JD5, who was not observed). C2, junior doctor two (JD2) and the specialist nurse were observed twice; junior doctors one (JD1) three (JD3) and four (JD4) were observed once. All the junior doctors observed were at least specialist registrar or clinical research fellow level. The specialist nurse was the only female member of the clinical team at either clinic (one of the research doctors at clinic two was also female but she did not provide clinical care during the study period). The nurse had a particular interest in nutrition and saw patients referred to her by the clinic doctors for secondary prevention advice and follow-up. She also saw patients whom she had identified as needing additional nursing follow-up from her ward visits<sup>viii</sup>.

Although observations were conducted over a similar number of visits at each clinic, in total, fewer consultations were observed at clinic two (reflecting a lower throughput of patients per doctor). At clinic two, consultations were slightly longer on average, with junior doctors nearly always having to wait to confer with the consultant before finishing the consultation. Consultations with 26 patients (10 women) were observed at clinic two. As anticipated, clinic two specifically targeted people suspected of having a TIA or mini stroke. Consequently these patients were slightly younger (aged 24 to 70 years) than those attending clinic one. Just under half (10/26) had never been admitted to hospital since they had ‘mild’ symptoms and were referred for specialist opinion by

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<sup>viii</sup> The role of the specialist stroke nurse is not clearly defined but may include aspects of health promotion, health education and coordination including secondary prevention.<sup>298</sup>

another doctor. These patients also had had less severe physical consequences and tended to be more mobile than those attending clinic one.

### **6.3. Social influences on secondary prevention management**

In the next section I discuss the main findings from the research. Although the aim was to identify both barriers and facilitators of ‘good’ risk management, in practice it was easier to identify barriers since well managed patients tended to be discharged as soon as their specialist stroke concerns were resolved. Equally, the literature to support the emerging themes largely focused on the negative rather than the positive aspects of professional practice. The themes presented here should be taken to represent social influences on the way secondary prevention is practiced rather than *errors* in practice made by individual clinicians.

Three types of social influences on secondary prevention management emerged from the data, (i) those relating to medical authority, its constraints on the consultation process, influence on the way in which notions of secondary prevention management were constructed and patient involvement in that process; (ii) structural barriers influencing continuity in service provision; and (iii) expectations of the roles of patients and problems addressing the needs of those who deviated from that role.

#### *6.3.1. Medical authority*

The first theme, ‘medical authority’ refers to the way in which social hierarchies (the status, training and responsibilities of health professionals) influence the delivery of care in the stroke clinic. Medical authority influenced the content and sequence of consultations; patient participation, particularly in relation to decision-making processes; and the professionals’ ability (and requirement) to share information with



patients. Depending on how ‘optimal’ secondary prevention is defined, medical authority acted either as a barrier to or a facilitator of ‘optimal’ management.

#### *6.3.1.1. The consultation process*

Consultations generally followed a common sequence of events beginning with a brief introduction and a chance for the professional to summarise existing information about the patient. Professionals then tried to open up the consultation by asking ‘And how have you been?’ Patients responded with details of current and past symptoms, problems they were experiencing (physical, psychological or social), or progress since the stroke or last consultation. In some cases this might include progress in managing secondary prevention such as success in quitting smoking. Then followed a sequence of detective work with professionals gathering and processing ‘evidence’ in order to construct a ‘profile’ of the patient, in terms of their health more generally but specifically in terms of ‘risk factors’ for stroke (a risk factor profile). Evidence for the profile was gathered from a number of sources including statements from the patient; from accompanying relatives (‘witness statements’); and professional statements from GPs or hospital professionals provided in the referral letter. The patient’s body itself was also used as evidence, with heart rate, blood, blood pressure and cholesterol all representing measurable sources of data, as well as the patient’s sensory body, its appearance and smell (for example being from an ethnic minority group, being overweight, smelling of tobacco smoke or alcohol). Smelling of smoke or alcohol might indicate that a patient was at risk from smoking and drinking, whilst looking overweight or being from an ethnic minority group might indicate that the patient’s diet put them at risk of high blood pressure or high cholesterol.



Professionals asked patients to relate the events that took place during and since the stroke. Patients provided descriptions about their families, occupation, interests and activities, medication use, smoking and alcohol consumption. The professionals directed these narratives, circumscribing what information was admissible, ensuring it was relevant to their clinical purpose (their own construction of risk). Statements from friends and relatives were used to ‘corroborate’ the evidence provided by the patient themselves, or as a surrogate for the patient’s statement in cases where patients had difficulty communicating. Questions about symptoms, risk factors, tests results and investigations were asked in a set order. Although no physical protocol or checklist was used, the order was standardised across consultations. At the neurology clinic, the trainee doctors reported the evidence they had gathered to the consultant, so that he could assess whether their detective work was adequate.

JD2: She is 56, a Caribbean woman, has a history of left numbness since 1996. She complains of waking at night with left leg numb and similar symptoms. [He goes on to discuss the symptoms]. She has had cardiac problems, hypertension which is checked by the GP, she is on drugs for high cholesterol. She is on aspirin, has a family history of diabetes and hypertension. Her blood pressure was 98/62; she has had dopplers and a CT scan.

Clinic 2-1; professional discussion outside the consultation

This standardisation helped professionals to ensure that they did not forget to ask anything important, since the information gathered had implications for interpreting what had happened and in making treatment decisions. Once all the evidence had been collated the professional assembled it into a risk profile of the patient. Professionals used the risk profile both to explain what had happened to the patient and to define an appropriate future course of action or treatment. For newly referred patients it was used in making a diagnosis.

Assembling the profile was a complex process, evidence collected from one source often contradicted that from another and professionals were required to judge which type of evidence was more accurate. Evidence from the patient's body (sensory signs and test results) tended to take priority over the patient's own account in defining the profile, as in the case of this patient who initially reported that he only smoked two cigarettes and drank two glasses of wine a day.

CI: 'I don't believe you, you are very heavily nicotine stained and smell of smoke and alcohol.'

Clinic 1-8; consultation 30

Different types of evidence had different value. At the top of the hierarchy were relatively uncommon pathologies generally diagnosed using technologically sophisticated tests or investigations needing particular expertise to interpret (such as rare neurological diseases and heart disease). Treatment usually involved surgical procedures or medical therapy. In the middle of the hierarchy were more common pathologies (high blood pressure, diabetes and high cholesterol) requiring tests to diagnose but more commonly tested and needing less expertise than those at the top of the hierarchy (possibly because they were less difficult to administer or interpret, less costly or more common place). Results from these tests were also commonly interpreted and discussed by the nurse, whilst those at the top of the hierarchy were not. At the bottom of the hierarchy were risky behaviours diagnosed from the patient's account and examination of their appearance. These included alcohol use, diet and exercise. These behaviours were not treatable with medical or surgical procedures and were less commonly used to define future risk. Every attempt appeared to be made to explore the risks at the top of the hierarchy before using those at the bottom to explain what had happened:

JD3: We need to check it's not cholesterol or diabetes and then we need to address other things such as lifestyle. The main thing [regarding lifestyle] is your smoking. I know that it's difficult but it could cause another stroke. We'll try and find other things which might have caused it...

Clinic 2-3; consultation 50

In some consultations, professionals talked about 'clinical evidence' to justify their risk evaluations. It was as though professionals needed to demonstrate their authority or expertise to the patient in discussing risk; 'evidence' was something restricted to the domain of professionals, as one doctor explained when evaluating the relative risks of surgery versus future stroke from narrowed arteries.

JD4: the narrowing on the left artery is 50% and the evidence that we have.... by 'we' I mean the medical fraternity has... you wouldn't normally operate on that level.

Clinic 2-7; consultation 61

The use of the term 'evidence' implies some sort of tangible proof but in practice the interpretation of patients' bodily signs and epidemiological statistics was more subjective, differing between different professionals. Some models of patient-centred consulting recommend that professionals' subjectivity be acknowledged,<sup>299</sup> but this appeared to conflict with the need for professionals to maintain their authority as experts and to uphold the notion that clinical evaluations are 'scientific'.

#### *6.3.1.2. Patient participation*

The rigid structure of consultations may have facilitated optimal secondary prevention management through ensuring standardised coverage of risk topics. However, it may also have acted as a barrier to patient participation. For example standardised formats of questioning may also have prevented professionals from tailoring consultations to the individual patient, or discouraged them from attending to the other aspects of the stroke



(such as recovery or social re-integration) and prevented patients from participating in the decision-making about treatment.

Once the risk factor profile had been assembled it was used both in understanding what had happened to the patient and in deciding on strategies for prevention or treatment. For certain risks, a range of treatment options was available, including medication and surgery. For others, professionals could only offer 'lifestyle' advice or refer patients elsewhere for such advice (to GPs, nurses, or specialist clinics). In general it was the professional who made decisions about treatment options based on the patient's risk profile and their own interpretation of best practice. However, such decisions were also influenced by a number of individual and social factors. For example, different treatment decisions reflected the status and expertise of the professional, with prevention strategies that required particular skills or qualifications (such as prescribing medication) being utilised by those at the top of the medical hierarchy (the hospital doctors) and the less technical aspects of prevention (such as providing lifestyle advice) being covered by lower status health professionals (nurses). Utilisation of particular prevention strategies was also influenced by personal interest. For example the nurse, who had a particular interest in nutrition dedicated much of her consultation to discussing diet, encouraging patients to eat less salt, more fruit and vegetables and cut down on foods high in saturated fat. The doctors rarely discussed such strategies, possibly because they were less skilled in doing so but also possibly because they were less interested in such areas.<sup>300</sup> One doctor justified his decision not to give diet advice suggesting that the net gain in terms of stroke prevention was not worth the costs to patient's happiness.

'Sometimes I don't really know what to say to people [about diet]...I don't believe in making people's life a misery ... they should be able to enjoy things in life, like pork chops

which won't do them that much harm.... maybe I should be strict but I don't think it is fair.' (Comment made to JR at the end of clinic 1-8).

Thus in some consultations patient happiness appeared to be a priority over and above risk control. Such allowances may represent the importance of medical authority in allowing professionals to be able to tailor secondary prevention management to the individual patient. However, it does conflict with population health goals, which do not allow for individual 'happiness' to be taken into account in providing treatment advice. Standardised turn-taking rules may also have discouraging patients from voicing their concerns. Patients sometimes initiated conversation but rarely asked direct questions of the doctor (on average three questions per consultation). By contrast, health professionals asked seventeen questions per consultation on average (ranging from 1-69). These were mainly related to the patients' history, or formed part of examinations such as 'ten quick questions' to test cognitive recovery. When patients did ask questions this was generally towards the end of the consultation after the diagnosis had been made and in response to information provided by professionals about diagnosis, explanations for what had happened and treatment instructions. In some cases the opportunity was used to request further investigations or a second opinion. However, patients tended to ask only about issues already broached by the professionals themselves. Where patients did attempt to discuss issues out of the usual sequence, professionals were quick to regain control of the consultation, redirecting it back on course. For example in consultation 47, the patient's wife tried to start the consultation by asking the consultant a question about the social services her husband had received. The consultant responded by saying 'Can I just go through things first and then you can ask questions at the end'. Although this approach to questioning does not in itself mean that secondary prevention was delivered in a 'sub-optimal' way, it does support previous studies suggesting that patients find it difficult to participate in consultations that are governed by professional



routines.<sup>301</sup> It also demonstrates the difficulty faced by doctors in reconciling their professional obligation to take an accurate and detailed history, with the ‘patient-centred’ need to encourage patients to become more involved in consultations.<sup>302</sup>

However, even when patients did manage to express a preference for a particular type of management strategy this was not necessarily incorporated into decisions about treatment.

C2: ... We ought to reduce the cholesterol a bit.

Patient: I did come off the medication, I wanted to try and get it down with these margarines but...

C2: [interrupts] No the medication actually reduces the risk

(clinic 2-5; consultant supervision of consultation with JD3)

In this consultation even though the patient expressed a preference to try non-pharmacological strategies to lower his cholesterol, medical authority ensured that that the professional’s opinion took preference and medication was subsequently prescribed.

#### *6.3.1.3. Information sharing*

While it may be a policy goal for patients to take responsibility for their secondary prevention management,<sup>254</sup> professionals did not routinely appear to share information with patients that would enable them to understand how to prevent a recurrence. This may have been because professionals were desensitised to patients’ needs regarding advice about secondary prevention management (such as informing them of operational aspects of health service management) and consequently did not think it necessary to provide such information. Alternatively it may have been as DiGiacomo suggested that they did not want their patients to be too ‘expert’ since expert patients may challenge professional authority.<sup>303</sup> Blood pressure results were mentioned in passing rather than relayed as important information needing to be understood and retained for future use,



the only exception to this rule being one patient who had clinical training (clinic 1-9; consultation 3). Actual blood pressure readings were only discussed in half (35/68) of the consultations and in most cases interpretation of measurements was not given (only 10/35). In some cases (13/68) blood pressure was not measured at all. After having her blood pressure checked by a doctor, one patient could not recall the result of the check in a consultation with the specialist nurse almost immediately afterwards.

Nurse: what is it [blood pressure] now?

Patient: They didn't say, they said it was higher but they didn't say

(clinic 2-8; consultation 65)

The patient went on to estimate that the measurement was 'Between 150 and 200 over something?' suggesting that the result had been provided but not necessarily understood.

By contrast, the nurse may have been less constrained by medical authority when sharing information. She did attempt to discuss strategies to help patients to take responsibility for their risk management, encouraging them to ask questions about their blood pressure. She recommended that they find out the blood pressure measurement and remember it so that they could inform other health professionals who might need to know. She also advised some patients that they should make their own decisions about control and even query the doctor's judgement if it conflicted with recognised guidelines.

What we recommend, the ideal blood pressure reading is no more than 145/85 whatever your age [she writes it on one of her secondary prevention leaflets] and sometimes you need to know that. This is new information, sometimes you get GPs who are old fashioned. He might say 'that's fine' but you need to say 'well I'm not happy about it!' (clinic 2-9; consultation 67)

Encouraging patients to query medical advice might have been an appropriate strategy had patients been able to voice their concerns but, if GP consultation processes are as influenced by medical authority, it is unlikely to be feasible in practice.

Although doctors seemed aware that newly referred patients had a lot of stroke related information to absorb, assumptions were made about the patient's knowledge of health service processes. Including about how to take tests, how to arrange appointments and how to gain prescriptions:

Patient: My tablet has run out.

C1: You didn't think to get any more from your doctor?

Patient: I had three tablets missing, I don't know how it works.

C1: I'm sorry I didn't explain it properly....(Clinic 1-7; consultation 25)

Medical authority may have also created language barriers to information sharing since professionals used technical language when giving instructions, which some patients did not understand.

One such example was information provided to two patients who were required to have blood tests conducted in order to assess control of high cholesterol and diabetes. In order to interpret the results of the blood tests, the patients had needed to 'fast' (not eat or drink anything except water for a specified period prior to the test, for example 12 hours prior). However, when each of these patients returned for follow-up appointments it was clear that the instruction to 'fast' prior to the test had not been understood. Since the patients had not fasted, they had to have blood tests repeated. In other examples the misunderstandings were over less technical instructions; for example the following patient did not realise that blood tests were conducted at a walk in clinic:

C2: ...we need the blood tests. [addresses the junior doctor] Has he had any done?

Patient: I had lots of papers.

C2: That was the blood tests. They're not appointments.

(clinic 2-3; consultation 52)

Since he had either not been told or not understood that he should go to a specific clinic the patient went home to wait for an appointment.

One possible explanation for the observed lack of information sharing is that professionals in their positions of authority were unaware of what information patients needed, how much information to provide and at what level the information needed to be pitched. Due to the consultation structure they had difficulty eliciting such details from patients themselves.

Professionals may also have had difficulty communicating their own concepts of risk to the patient in a meaningful way. In the clinical literature concepts of risk tend to be discussed in terms of statistical probability or chance, which may be difficult to translate to a lay audience.<sup>304,305</sup> Some professionals were more comfortable discussing risk profiles than others, so information sharing appeared to be an individual skill. As with the descriptions of tests results, doctors mostly described future risks as 'high' or 'low' but sometimes backed up their predictions with statistical values or estimates of risk to stress the point. Such information was sometimes confusing for patients and when they queried what doctors meant by their explanations of risk, the explanations became increasingly unclear. While it may have been relatively simple to provide a probability estimate of population risk, it appeared to be more difficult to interpret and communicate such estimates in a meaningful way for the patient.

Patient: Can you say what the risk is of having another one?

JD4: I can't personally give you an estimate...your risk of stroke doesn't turn back to the same risk as before, for several years. But I can't give you a likelihood figure but it's higher than for the general population. If you said 'do you think I will have another stroke in my life, or in the next 5 years' I would probably say not. But statistically you could.

(Clinic 2-7; consultation 61)



Risk was rarely presented to patients in an 'objective' fashion but instead used as a tool to persuade patients to engage in secondary prevention strategies or to legitimise the message the professional wanted to get across. In the above extract, risk discourse was used as negative reinforcement to frighten the patient into complying with the doctor's wishes. However, discussion of risk was also used as a means of providing positive reinforcement:

Patient: If it carries on like this, I could have another one [stroke] tomorrow, there're no guarantees?

JD2: I wouldn't say – with all these things controlled [your risk is] much reduced. You were smoking [quite a lot] at the time weren't you? Twenty-five a day is quite heavy.

Patient: I know it hasn't cured the risk but it's reduced the risks?

JD2: Oh much reduced.

(Clinic 2-6; consultation 56)

One mechanism for sharing information with patients is written information. There was a clear difference between the clinics on their policy for providing written information during the consultation. Professionals at Clinic 2 routinely handed out an information leaflet on stroke secondary prevention to their patients (published by a national stroke charity) but similar information was never issued during consultations at Clinic 1. It is difficult to explain why the policies at the two clinics differed other than that at Clinic 1, since more patients had been seen previously on the ward, written information may have been distributed at that time rather than in the outpatient clinic. However, eight patients attending Clinic 1 were newly referred and would not have received information previously.

### *6.3.2. Structural influences on continuity of care*

The second theme ‘structural influences’ refers to the influence of health service organisation on the ability of patients and professionals to carry out recommended secondary prevention activities. Similar to the ‘system induced setbacks’ identified by Hart,<sup>297</sup> many of the emerging barriers to delivering secondary prevention related to problems of continuity between health and social services. Three key problems emerged, those related to assumptions about health care as a ‘seamless service’, those related to the way the specialists delivered secondary prevention advice as a ‘one off dose’ and those related to the problem of multiple providers being involved in patient care.

#### *6.3.2.1. A seamless service*

Although not explicitly stated, strategies for delivering secondary prevention management are based on the assumption that health care is provided in a seamless system, with tidy overlap between different sectors. For example, in prescribing medication professionals reassured patients that information was shared across hospital and community services:

C1: Your blood pressure is much too high, it’s not surprising as you haven’t been taking [your tablets]. You mustn’t run out.

Patient: How do I not run out?

C1: Go to your own doctor.

Patient: Does he know about it?

C1: Yes he does...(Clinic1-7, consultation 25)

Both professionals and patients discussed health care services as if continuity was expected. However, in some cases their experiences of care suggested that assumptions were misplaced. For instance information sent to other providers did not necessarily

lead to action, as in the case of this patient who had been referred to the addiction clinic to aid smoking cessation

JD4: Are you still on cigarettes?

Patient: Yes I am. I was supposed to be seen in the addiction clinic but they didn't send me an appointment (Clinic 2-7 consultation 59)

In rare cases professionals explicitly acknowledged that there were problems with continuity in service provision, sometimes compensating for problems with other services by changing their own practice. One doctor explained (to me) that he would retain a patient for additional monitoring at the clinic if he felt the GP would not monitor them properly (Clinic 1-1).

However, the extent to which professionals were able to compensate for poor continuity in services was limited by the type of problem experienced by the patient and the structure of services. Problems with social services were more difficult for professionals to address. For example, one patient who had experienced difficulty getting the steps outside his house adapted to enable him to get to and from his home more easily (influencing his ability to get prescriptions or engage in exercise to prevent stroke recurrence) could not be helped by the clinic professional. Since health service structures place housing issues outside the remit of health professionals it was not possible in this case for the professional to address the secondary prevention needs of the patient. Thus the structure of services had the ability to act as a barrier to optimal care, limiting professionals' abilities to address population health goals and in allowing them to delivered patient-centred secondary prevention.

#### *6.3.2.2. Multiple providers*

People with stroke often have multiple illnesses and may be cared for by different health care specialists. This gave professionals the opportunity to defer responsibility for



secondary prevention management to others. In some cases, aspects of secondary prevention were neglected, professionals indicating that secondary prevention would be addressed elsewhere. Even when patients made it clear that the advice they had received elsewhere was not satisfactory, their queries were not always addressed. In one consultation a patient previously prescribed Amlodipine (a calcium channel blocker which can be used to lower blood pressure or as a treatment for angina) by a cardiologist requested additional information about the medication. The doctor appeared unwilling to answer the patient's questions, saying 'I don't want to get involved in the treatment' (Clinic 2-5). In other cases there seemed to have been an assumption that advice would be better provided elsewhere:

JD1: A couple of things: you have to try and stop smoking.

Patient: It's awful hard.

JD1: I know but...you have had a stroke at 48. It's your only chance to stop what happened to your mother. If you think you want more help, talk to your GP.

Patient: [laughs]

Patient's wife: We'll get you a new GP.

JD1: It's more in their realm – if you need patches or support groups.

(Clinic 2-6, consultation 56)

#### *6.3.2.3. A single-dose approach*

Professionals also appeared to view secondary prevention as cumulative, being delivered over time in different consultations and by different professionals. If a particular issue was not covered in one consultation, it was assumed that the issue would be addressed in subsequent consultations. One doctor explained (to me) that he did not see providing too much or too little information as a problem since patients could be recalled for subsequent visits to cover aspects of secondary prevention not previously understood. In practice, secondary prevention advice delivered in the initial

consultation was not repeated unless the patient expressed concern that something was wrong. In one consultation the specialist stated upfront to the patient (and to me) that he did not intend to cover secondary prevention in the current consultation because he had covered it in their last meeting and this consultation was about a recent fall she had had.

C1: We went over everything last time about your stroke and what we need to do to avoid [another one]. (Clinic 1-3, consultation 7)

In other words, despite the physical opportunity to make secondary prevention ongoing, there appeared to be an assumption that a single transfer of advice in a consultation was sufficient. Only if problems with management were explicitly raised would subsequent ‘doses’ of advice be provided. The nurse explained how organisational structures promoted this single dose approach. She said that in conducting her ward consultations, she was required to make a record in the patient’s notes if she had discussed secondary prevention with the patient. Having ‘ticked the box’, the patient would not then be re-referred for additional advice at the stroke clinic, since it was assumed that their secondary prevention needs had been met in this one-off consultation. She was concerned that this structured referral system prevented her from ensuring her patients had properly understood the messages she had delivered and recounted an example of a patient whom she later saw regarding an unrelated matter who could not recall ever being given secondary prevention advice by her.

### *6.3.3. Expectations of the patient role*

The third category of social influences on secondary prevention delivery relates to expectations of the patient role and the reactions to those who deviate from the expected role. In particular, expectations influenced how risk profiles were represented to patients, which may have helped or limited the patient’s ability to engage in secondary prevention activities.



### *6.3.3.1. Being a good patient*

Consultations entailed the classification of patients into those who were ‘good’ and those who were not. A number of studies have defined ‘good’ patients in terms of their ability to act out what Parsons defined as the ‘sick’ role.<sup>303,306-308</sup> Lorber defined good patients as those with the ability to comply with doctors’ orders,<sup>308</sup> whilst for Jeffery they were those who were clinically interesting and not socially deviant.<sup>307</sup> DiGiacomo reflected on her experience of cancer treatment and suggested that being a good patient also involved remaining ignorant of clinical practice and not challenging professional judgements.<sup>303</sup> In the stroke clinic consultations classification was not always explicit but could be discerned from compliance related discourse.

Although the shift from a compliance model of prescribing to a concordance model suggests mutual agreement in decision-making,<sup>265</sup> stroke professionals did not distinguish between the two concepts. Concordance was discussed as if it was just the latest word for compliance, as one doctor commented ‘I know your compliance is not good, I mean your concordance!’ If the doctor had felt that the patient’s tablet taking behaviour was related to mutual agreement, then presumably he would have used the phrase ‘our concordance’ rather than using the phrase ‘your concordance’ which suggests that tablet taking (or lack of it) was the patient’s responsibility alone. In some cases patients were reprimanded if they failed to comply with advice or treatment such as taking tablets:

Patient’s son: She doesn’t take her tablets because she has had diarrhoea. She was on dipyridamole and Lisinopril but she wasn’t taking them

C1: What about aspirin?

Patient’s son: The way I understood it aspirin was not recommended because of her stomach problem.



C1: Because she was taking aspirin at the time of the attack, that is why I put her on dipyridamole and Lisinopril. She needs to be on a platelet drug.

The conversation continued until the doctor came to a decision

C1: I think what I will do is put you back on aspirin now. If you have any more attacks or loss of speech come back and we will put you on other tablets. We are trying to prevent you having a major stroke where you can't speak ever again. You have to take it seriously – it's not a joke.

(Clinic 1-6; consultation 20)

Such reprimands are reminiscent of psychological theories of behaviour change through operant conditioning,<sup>309</sup> whereby good behaviour is reinforced with praise and bad behaviour chastised or punished. Some patients and their carers highlighted how compliant they were to the doctor, stressing their own good behaviour suggesting that this 'reinforcement' may have encouraged patients to follow the doctor's advice, thus facilitating optimal secondary prevention.

However, there is much in the psychological literature about the limitations of punishment as a means to achieving behaviour change and in these consultations reprimands may have ultimately acted as a barrier to optimal secondary prevention since some patients may have deliberately withheld information from professionals for fear of judgement or reprimand. This was illustrated in one consultation, where a patient tried to withhold information about the amount he smoked and drank. Initially he reported that he smoked only two cigarettes and drank two cans of Guinness a day. He justified his apparent changed lifestyle by saying that he could no longer afford to drink or smoke the amount he had done previously. However, later in the consultation he admitted smoking and drinking more than he had earlier stated.

C1: Are you really only smoking 2 a day with yellow nails like that?

Patient: It was a lot worse

C1: How much have you had to drink today?

Patient: One glass of red wine today at about 12.30.

C1: How much wine are you drinking?

Patient: 1 small bottle, only 3 glasses.

C1: In addition to the Guinness?

Patient: No.

C1: How many cigarettes have you had today?

Patient: Five or six.

(clinic 1-8; consultation 30)

Professionals expressed their frustration with patients whom they later exposed as having hidden information from them, through their manner and what they said. In the case presented above the patient's fear of reprimand was justified since the professional subsequently accused him of telling lies and warned him that his life would be in danger if he did not make more of an effort to stop smoking and drinking.

#### *6.3.3.2. Commitment to secondary prevention*

In addition to apportioning blame, judgements about patients' behaviour were used in making decisions about providing information or services, defined by Lorber as professional 'labelling' of patients.<sup>308</sup> In the outpatient consultations, management decisions appeared to be based on assumptions about patient commitment. If the patient did not demonstrate enough commitment to stroke prevention then professionals were able to withhold further services (such as further follow-up or referral to other specialist services including the addiction clinic).

Doctor: Is it worth making another appointment for me to see you again knowing that you'll have to see me if you haven't given up smoking?

Patient: yes.

Doctor: I'll see you in 2 months. You must have given up smoking for at least a month by then.

(clinic 1-5, consultation 14)

Whilst professionals routinely stressed the importance of stroke secondary prevention, some patients queried aspects of their medical care, resisting the clinician's advice or treatment. One patient queried being hospitalised for stroke prevention investigations given his family commitments and given it had taken four months to get an appointment at the stroke clinic:

Patient: As far as the medication goes, I had the stroke in January and haven't been seen until now. I would have thought [if it was urgent] I would have been dealt with more quickly. I'm sorry but the urgency has gone out of the situation.

(clinic 2-7; consultation 57)

These differences reflect what has been described as differences between the medical-world view and the patient's experience<sup>310</sup> and again highlight the conflict between patients' needs, wants and preferences and optimal secondary prevention practice to achieve public health goals. 'Good' patients were happy to conceptualise their stroke using the medical-world view. By contrast, 'difficult' patients were those who resisted taking on the expected role and the responsibilities associated with being a stroke patient (such as taking medication). Tensions appeared to exist when there was a mismatch in the way patients and professionals viewed the stroke experience. Previous researchers have suggested that patients may determine the impact of the stroke by evaluating it in relation to what their life was like before the stroke rather than against some objective measure of functioning.<sup>119</sup> In this study some patients found it difficult to come to terms with what had happened to them, even if they were relatively independent.

Patient: Don't get me wrong I'm not looking for miracles, I just thought something else could be done.

Cl: You can almost certainly have an aspirin tablet every day so get onto that as soon as possible.

Patient: As well as the cholesterol [tablet]?



C1: It doesn't matter what size or shape.

Patient: Until now I've never taken a tablet in my life.

C1: [dismissively] Well I'm sorry about that.

(Clinic 1-7; consultation 23)

Ultimately tensions between patients and professionals may have been detrimental both in terms of delivering patient-centred care and in relation to optimal secondary prevention management. Although patients had little opportunity to voice their concerns, they were able to express their dissatisfaction with doctor's decisions through other means, including not taking their treatment. Patients might stop taking their medication if they felt that the drugs were potentially harmful, if they were experiencing unpleasant side effects from the drugs, or if they feared being stigmatised by them.

Patient: At the moment I'm taking them [antiplatelet tablets] every day. Is it really necessary?...It looks bad on the medical record or if you tell people'.

(clinic 2-9; consultation 55)

In the case of this younger patient (age 24), medication represented being ill and she was not happy to be defined in terms of her stroke.

#### *6.3.3.3. Ability to conform to the patient role*

For Lorber, a good patient is one who follows doctors' orders.<sup>308</sup> However, fulfilling the sick role in relation to secondary prevention management also meant being informed about stroke risk factor control. 'Good' patients had developed strategies to demonstrate their ability to assist the doctor in developing their risk profiles such as bringing along their current medication in a carrier bag (clinic 1-2; consultation 5) or producing printouts from home blood pressure kits (clinic 1-9; consultation 34). They were used to the medical system, understood the 'ceremonial order' of consultations,<sup>311</sup> including knowing what to do, when to speak and what to say.

C1: How have you been keeping?

Patient: Fine [patient hands over some test results to the doctor]

C1: well your cholesterol is up a bit, I haven't chased you about that.

Patient: It was up originally, I was allergic to statins, the GP tried 2 or 3 times and came to the conclusion that I couldn't successfully take statins. I can't afford to have mal-absorption of anti-hypertensive drugs. Since Christmas I've taken a drug called Propanolol and take an anti-hypertensive at 5 o' clock...

(clinic 1-9; consultation 34)

One reason why some patients had difficulty adopting the sick role may have been that they did not understand enough about health service processes, secondary prevention, or clinical terminology. For instance, some patients were not used to the methods of questioning used in consultations, making it hard for professionals to elicit the information they needed:

C1: do you take your tablets?

Patient: yes.

C1: how often do you forget them?

Patient: the tablets give me constipation.

C1: so you don't take them?

Patient: I have to take them but I can't help it if [I have constipation] there's nothing I can do.

C1: that's not necessarily the case but I need to know if you aren't taking them because there is no point prescribing more if you don't take them most of the time.

(Clinic 1-3; consultation 8)

Lack of patient competencies may be explained by the lack of technical expertise that patients had. For example, one patient on seeing the result of the CT scan of her brain displayed on the wall (showing a cross-sectional image of her brain) commented, 'You'd have to be very clever to understand that', to which the doctor replied 'not really'. However, technical expertise was not necessarily a requirement for being a good patient. Some patients participated in discussions of secondary prevention without

referring to technical terms, using their own words to describe the drugs they were taking and what they were for:

C1: Your blood pressure is the same as last time so if [the tablet is] causing you side effects you may as well stop it and try something else.

Patient: the triangular ones?

C1: No, the other ones.

Patient: No, I only take the triangular ones.

(clinic 1-6; consultation 18)

## **6.4. Discussion**

In this chapter I have presented research conducted as part of the theoretical phase of the Stop Stroke study, to investigate the delivery of secondary prevention strategies in the stroke clinic. Although the aim of the research was to uncover barriers and solutions to the problem of delivering ‘optimal’ secondary prevention management, this was difficult to do through observation alone. For example it was not possible to know what impact the clinic activities had on risk factor control once the patient had left the consultation. Equally, it was not so easy to draw out recommendations for ‘optimal’ management, since in some ways ‘optimal’ patient-centred practices seemed to conflict with ‘optimal’ best practice recommendations. However, if the stroke clinic is a place for delivering secondary prevention strategies then three types of social influences were identified which may act as barriers to achieving optimal care (however defined): those related to medical authority and the way this shapes consultations; structural barriers resulting from current organisation of services; and expectations of the patient role.

Incorporating the patient’s experience of illness into the consultation is a common characteristic of models of patient-centred care.<sup>258,260,299</sup> However, this appeared problematic in the context of the stroke clinic where the key purpose of the clinics



appeared to be to provide specialists with an opportunity to form risk factor profiles of their patients. These were used both in understanding what had happened to the patient, in making decisions about the patient's future and in persuading patients of the importance of engaging in particular secondary prevention strategies. To ensure that clinically important evidence was not missed, consultations were directed in a standardised way with the focus being largely on the biological (rather than the psychological or social) aspects of stroke risk management. However, while this may have facilitated the profiling process it may also have limited the professionals' ability to incorporate the patient's illness perspective since standardisation discouraged patients from participating in consultations. If patients are unable to express their point of view, or when they do it is ignored, then this clearly presents problems for achieving patient-centred management. However, excluding patients' views may ultimately limit the professionals' ability to choose strategies appropriate for a particular patient.

Kleinman et al., proposed a process of 'negotiation' to uncover the patient's concerns in relation to their illness experience and mediate between the different viewpoints of patients and professionals.<sup>312</sup> However, to deviate from the standardised consultation format might have comprised the professional's ability to form a comprehensive risk profile upon which all other clinic decisions were based. Deviation from the professionals' area of expertise may also have presented challenges to medical status since on uncovering psychological or social health concerns (such as problems with access to community services to aid risk factor management), professionals were unable or unwilling to try to resolve them.

The ability of individual health professionals to overcome the constraints of medical authority is likely to be limited. In this study, professionals did try to ask patients if they had any concerns they wished to discuss but patients rarely responded and where they

did, medical authority ensured the prioritisation of measurable physical or psychological outcomes over other aspects of health and well-being. Since even those not related to the health system such as researchers can have problems uncovering patient concerns and preferences,<sup>313</sup> it is not surprising that health professionals find it particularly difficult operating within positions of authority and would continue to find it difficult even if they as individuals tried to adopt a more patient-centred 'style' of consulting. If clinicians are to identify with patients' experiences of risk management then social and cultural barriers need to be removed: either differences in authority between patients and health professionals need to be reconciled; or new ways of eliciting patient preferences outside of current clinical format need to be found.

Medical authority also had an impact on the patient's ability to share in decision-making processes (another important component of many patient-centred care models). Even when patients did indicate their preferences for specific treatment options, professionals appeared to make few attempts to incorporate them into the decision-making process. The difference between compliance and concordance appeared not to be properly understood by professionals, who seemed to encourage patients to agree with their own preferences rather than to find a mutual understanding that suited both parties (something Jones defines as a 'gift wrapped' version of compliance<sup>264</sup>). If a shared consulting style encompasses recognising patient autonomy<sup>260</sup> then the stroke clinic practices do not fit the patient-centred care model. Here autonomy was only supported if patient decisions concurred with clinical preferences. There appeared to be an implicit expectation that patients do what they are told, conform to a sick role and demonstrate commitment to secondary prevention. Yet this appeared to be at odds with the notion of a shared approach to decision making. Neither did professionals routinely provide information that would enable patients to share in decisions (the written information



provided by professionals at clinic two included only general facts about stroke rather than detailed advice to allow patients to participate in choices). Similar contradictions can be identified in the rhetoric of the recent UK government initiative to develop 'expert patients'.<sup>314</sup> Whilst the initiative claims to be about improving the lives of patients with chronic disease and not about compliance, the discourse on its vision includes achieving public health goals, for instance encouraging patients to 'use health promoting strategies (improving diet, exercise and weight control)' as well as using fewer services. Rather than being a problem of consulting style, lack of negotiation in consultations may reflect tensions between the concept of patient-centredness and the goals of risk management. In order to incorporate patient preferences, professionals would need to prioritise patients' concerns over and above population and professional priorities (including risk management), regardless of the impact of doing so on traditional health outcomes.

In the outpatient setting, the relationships between the professionals and most of the patients were of relatively short duration making it difficult for them to develop in a way that could promote personalised care. Most patients were seen only once by the professional during the course of the study and one-off appointments such as these may not have been enough to develop the relationships necessary to facilitate effective ongoing risk management. The purpose of the consultation appeared to be to address all the patient's stroke needs and then discharge them elsewhere (to a GP or other specialist) and consequently there was little continuity, secondary prevention being provided by many different professionals. Although the clinic provided a centralised place for the identification of issues for disease management after stroke, it did not provide a forum for continued care or for tackling non disease-related aspects of health. This in turn prevented professionals from providing aspects of patient-centred care and



monitoring risk factors over the longer term. Patients were subsequently prevented from being able to successfully negotiate health services, receive appropriate risk factor advice and participate in decisions about their care.

#### *6.4.1. Summary*

The findings presented in this chapter demonstrate how qualitative observational methods can be used to investigate health service delivery and generate hypotheses for use in intervention development. This ‘formative’ research in the stroke clinics was conducted to provide a better understanding of the process of delivering secondary prevention strategies, highlighting problems with medical authority, service structures and expectations of patients implicit within current practice. Depending on how ‘optimal management’ is defined these processes may act as barriers to public health goals for optimal risk factor control or barriers to patient-centred care. Exactly how these findings influenced the development of the Stop Stroke intervention will be investigated in subsequent chapters.

## **Chapter 7. The MRC Framework in Intervention Development**

In this chapter I present a description of the Stop Stroke intervention package and its development (the modelling and exploratory trial phases outlined in the MRC Framework). The focus of the chapter is on understanding how the concept of the intervention and its components were developed. We have already seen the findings from some of the theoretical work conducted to inform intervention development and in this chapter I explore the extent to which the intervention was theoretically grounded. This in turn provides an insight into factors and processes that might influence the eventual success or failure of the intervention.

### **7.1. Introduction**

Development of the intervention began in 1999 when the protocol for the study was accepted for funding and continued until July 2003 when the main RCT started. Development during this time period is presented in this chapter. Funding for intervention development was provided by a UK national charity, The Stroke Association, in the form of the first five years of a 10-year programme grant, totalling £251,271. This covered funding for a junior research associate (JR for the first three years) and research costs. The first two years of funding were allocated for theoretical work and intervention development; the remaining three were allocated for the main RCT evaluation, although in practice, the RCT did not start until year four.

The methods for this chapter are presented in Chapter 4, section 4.4. To summarise, participant observation was conducted from the start of the development phase with detailed field notes taken on interactions between staff, correspondence and meeting minutes collated and analysed thematically. The results are divided into four sections:

development of the intervention concept; development of the intervention components; the exploratory trial; and a discussion of the development process.

## **7.2. Participants**

A multi-disciplinary group was involved in the development of the intervention with diversity in discipline and skill mix. They included a core group involved throughout the four years of development, with others participating in an ad-hoc manner at different stages of the development process (Table 10).

### *7.2.1. The core investigators*

The core group of investigators included the principal investigator, a clinically trained senior researcher in public health medicine with a special interest in stroke (PI); two other key investigators: a social researcher with a background in social anthropology and an interest in stroke illness (I1); a senior stroke physician (I2); and a junior statistician (later promoted to senior level SS1). All had previous experience of working on at least one complex RCT study. Although I was not one of the original investigators, I feel that I was still part of the core group since I was involved in the study almost from its conception and was involved throughout the first four years of theoretical phase research and intervention development. I had an MSc in health psychology and several years' research experience but no practical experience of complex intervention development or RCT evaluation.

### *7.2.2. Advisors during the theoretical phase*

During the first two years of development the core investigators were supported by a junior statistician who provided advice on analysis of the SLSR (JS1). In addition,



**Table 10. Staff involved in intervention development.**

<b>Participant</b>	<b>Status</b>	<b>Role in intervention development</b>	<b>Phases of development</b>
PI	Senior clinical researcher in public health	Principal Investigator for the programme	All phases
I1	Research Fellow in social anthropology	Key Investigator on the programme	All phases
I2	Lead stroke physician	Key Investigator	All phases
JR	Research Associate (background in health psychology)	Main researcher in the theoretical and modelling phases	All phases
JS1	Research Associate (statistics)	Statistician for the SLSR	Theoretical phase
SS1	Research Fellow / Senior statistician	Statistician for the SLSR	Modelling phase
SS2	Senior Statistician	Steering group member	Theoretical and modelling phases
PHS1	Clinical Public Health Specialist	Steering group member	Theoretical and modelling phases
N1	Senior Nursing Researcher	Steering group member	Theoretical and modelling phases
PS1	Professor of Stroke Medicine	Steering group member	Theoretical and modelling phases
N2	Senior Nursing Researcher	Steering group member	Theoretical and modelling phases
GP1	GP	Steering group member	Theoretical and modelling phases

Participant	Status	Role in intervention development	Phases of development
PHT	Public Health Trainee	Researcher responsible for pilot testing the intervention	Modelling and exploratory trial phases
TC	Administrative Assistant	Stop Stroke Trial coordinator, involved in setting up the trial	Modelling phase
RA	Research Assistant	Stop Stroke Trial researcher responsible gaining patient feedback on the intervention	Modelling phase
JS2	Statistician	SLSR statistician	Modelling phase
JS3	Statistician	SLSR statistician	Modelling phase
US	Statistician	Statistician with expertise in cluster RCTs	Modelling phase
SPR1	Research Fellow/Junior Doctor	Clinical SLSR fieldworker	Modelling phase
SPR2	Research Fellow/Junior Doctor	Clinical SLSR fieldworker	Modelling phase
SPR3	Research Fellow/Junior Doctor	Clinical SLSR fieldworker	Modelling phase
SPR4	Research Fellow/Junior Doctor	Clinical SLSR fieldworker	Modelling phase
SPR5	Research Fellow/Trainee GP	Clinical SLSR fieldworker	Modelling phase
NC1	Research Associate	Non-clinical SLSR fieldworker	Modelling phase

Participant	Status	Role in intervention development	Phases of development
FUP1	Research Associate	Non-clinical SLSR fieldworker	Modelling phase
Admin1	Administrative Assistant	Coordinator for the SLSR	Modelling phase
PHS2	Senior Clinical Public Health Specialist	Trial advisory group	Modelling phase
SL	Expert in speech and language therapy	Trial advisory group	Modelling phase
GP2	GP with an interest in stroke	Trial advisory group	Modelling phase
GP3	GP, head of local PCT	Trial advisory group	Modelling phase



support was provided by a steering group. This included two senior nursing researchers (N1, N2), two clinical professors of stroke medicine (PS1 and PS2), a GP (GP1), a senior statistician (SS2) and a clinical public health specialist (PHS1). The steering group met on two occasions, once after a year of the study in August 2000 and a second meeting when the shape of intervention was proposed in April 2001.

### *7.2.3. Advisors during the latter stages of intervention development*

Once the intervention had been designed, a second steering group was formed. This steering group was responsible for advising on matters relating to the main RCT evaluation but also had some input into intervention design (at the steering group meeting held in 2003 before the start of the trial). This group included the senior statistician from the previous steering group (SS2); two GPs, one who was head of one of the local primary care trusts (GP2) and one who had a particular interest in stroke (GP3); an expert in speech and language difficulties (SL); and a senior clinical public health specialist (PHS2).

### *7.2.4. Investigators involved in the modelling and exploratory trial phases*

During the modelling phase additional people became involved in the intervention design. A public health trainee was employed with responsibility for evaluating written materials produced for part of the intervention and for conducting the exploratory trial (PHT). Two staff, a trial coordinator (TC) and a research assistant (RA) were employed to work on the main RCT but also contributed in the development phases: the TC was involved in administrative aspects of setting up the trial; the RA was involved in evaluating patient information literature. Neither the TC nor the RA had any previous experience of working on a RCT. The TC had previously worked as a programme

coordinator at a London business school. The RA had no previous research experience but had received research methods training from her MSc in health psychology.

The remaining staff involved in intervention development all worked on other projects within the stroke team. These included two statisticians (JS3 and JS4), five junior doctors (SPR1, SPR2, SPR3, SPR4, SPR5) and three non-clinical staff (NC1, Admin1 and FUP1). A third statistician who was not a member of the stroke team (US) also provided advice during the modelling phase. He had special expertise in cluster RCT methods. Table 10 summarises the staff participating in intervention development.

### **7.3. Developing the intervention concept**

According to the MRC Framework, the design of the intervention should have emerged from theoretical phase findings. But while theoretical phase findings did guide aspects of intervention development, in practice, design was also influenced by other factors. It was clear from the timeline of events that the key investigators already had ideas about the shape of the intervention even prior to the start of the theoretical phase, meaning that intervention development was not strictly an ‘inductive’ process.<sup>315</sup>

#### *7.3.1 Synthesising theoretical phase findings*

The first part of the theoretical phase involved conducting a literature review to investigate previous multiple risk factor interventions in chronic disease,<sup>124</sup> but it was decided at the outset of the study, that the intervention would not involve placing another individual (such as a nurse or support worker) into the health system. Recent published studies of such interventions suggested that they had limited efficacy<sup>251,252,316</sup> and there was no evidence that placing additional health professionals into the system would necessarily solve the problems of coordination between primary and secondary

care, or reach those patients who did not currently access services. Creating an intervention based on one individual also had resource implications for rolling out the intervention if it proved successful.

The theoretical phase of intervention development was conducted between March 1999 and April 2001. In addition to the theoretical work already discussed (literature review, qualitative investigations and SLSR analyses),<sup>34,214,215</sup> an investigation of patient information literature was conducted (unpublished). At this stage, analysis of qualitative data was limited by time and cost. Since only one year's funding had been allocated for completion of all four components of the theoretical phase, it was not possible to conduct a thorough theoretical analysis prior to the development of the intervention itself. Instead a rapid assessment was conducted.<sup>317</sup> As the researcher on the project, it was my responsibility to collate findings from each part of the research phase and to compile a list of facilitators and barriers to secondary prevention. For each barrier I suggested a number of potential solutions, which were then presented to the other key investigators for consideration. Our aim was to define a potential intervention, which could tackle the multiple barriers to secondary prevention.

Although data collection was still ongoing, initial findings suggested that barriers to secondary prevention were multiple (see Chapters 5 and 6) relating to individual factors (patient and professional conceptualisation of stroke secondary prevention and poor communication of secondary prevention advice); and organisational factors (organisation of stroke services, lack of coordination between primary and secondary care). Preliminary theoretical phase findings suggested that an intervention focusing on one specific problem such as the coordination of care would be insufficient. To improve risk factor management for all stroke patients the findings suggested that an intervention with multiple components was required, one that would promote an understanding of



stroke as a chronic disease and be tailored to account for each individual patient's secondary prevention needs and experiences.

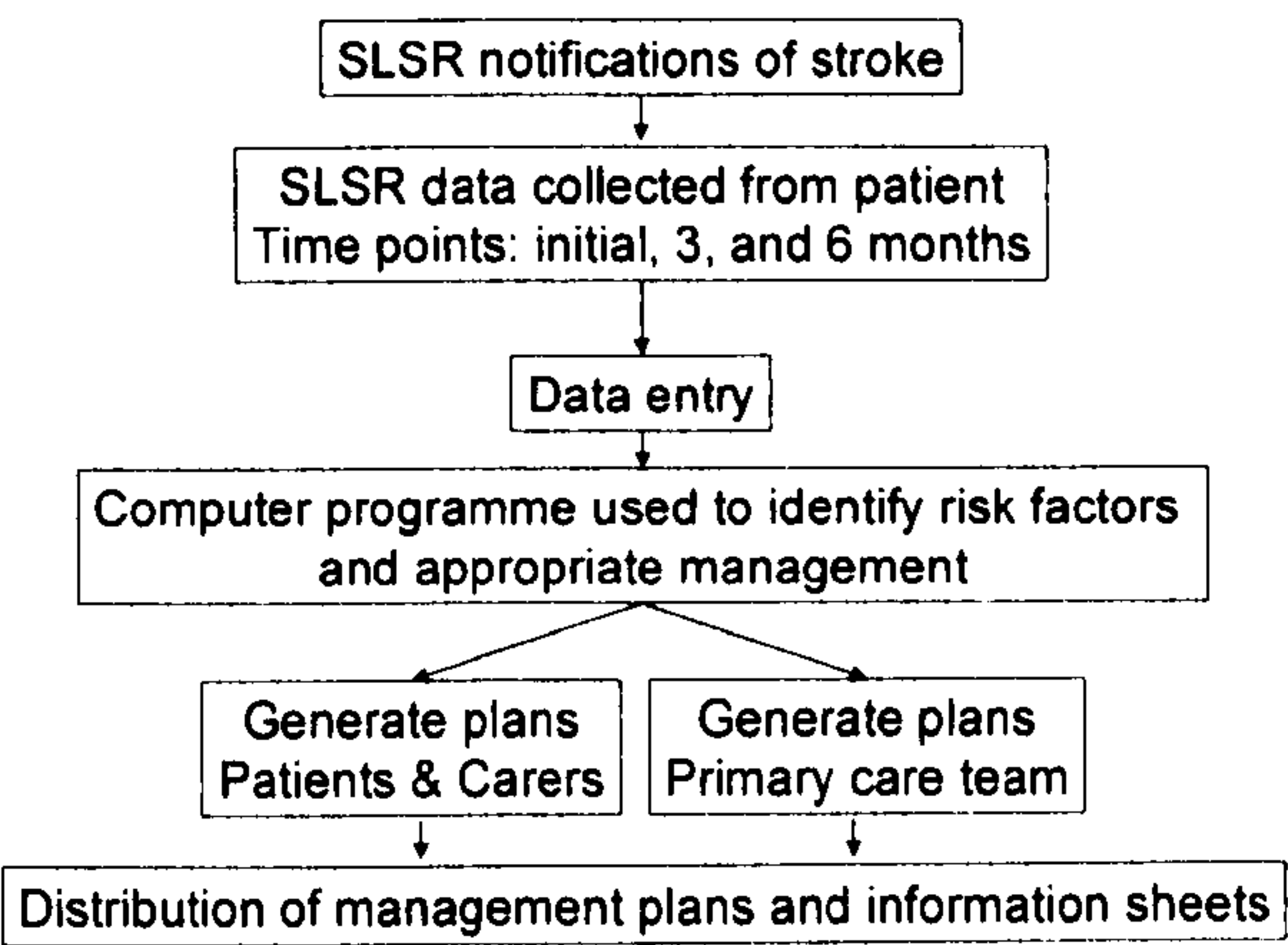
### *7.3.2. Using the SLSR as a tool for intervention*

The decision to make use of the SLSR,<sup>17</sup> the team's ongoing population register of first in a lifetime strokes, as a tool for intervention was made early on in the intervention development process. The initial suggestion was presented by the PI at the first steering group meeting in April 2000 mid-way into the theoretical phase. Although the theoretical phase did not drive the decision, since the SLSR was an ongoing resource for identifying stroke patients and following them up at multiple time-points, the core investigators felt that it could potentially be adapted as a mechanism for delivering secondary prevention.

In March 2001 an experimental phase started. I began to design an outline of a secondary prevention plan for patients that could contain individualised risk factor information from the SLSR. The design was a single sided A4 sheet listing the individual patient's risk factors. The list included those risk factors that the clinicians considered to be most important for preventing a future stroke. At the same time, collaborative talks were conducted with a team in another academic department who had created software to provide similar information for GPs about their patient's diabetes (Diabeta-3).<sup>318</sup> The possibility of linking with Diabeta-3 was discussed but it was decided that the Stop Stroke intervention should stand alone since there had been problems of uptake of the Diabeta-3 computer software in GP practices. In the case of stroke where each GP only saw 1-2 patients per year, the software appeared impractical. At the second Stop Stroke Programme steering group in June 2001 the collated findings from the theoretical phase were presented together with a proposal for the intervention

itself drafted by the key investigators and me. It was agreed at the meeting that the intervention would ‘dovetail’ with the SLSR and target both patients and professionals. Tailored secondary prevention plans (derived from SLSR data) would be produced and delivered to patients and carers. In addition, the patient’s GP would receive a plan tailored to their patient, together with academic visits from expert clinicians<sup>319</sup> (the lead stroke physician and the PI) providing information on the intervention and local stroke issues. Data collected by the register (clinical, socio-demographic and service data related to the stroke) would be transformed to provide an individualised secondary prevention package for patients, carers and health care professionals at three time points post stroke. The aims of the intervention were four-fold: i) to make the screening of risk factors and delivery of secondary prevention advice ongoing, encouraging patients and professionals to conceptualise stroke as a chronic disease rather than an acute event; ii) to standardise the delivery of secondary prevention advice to ensure that all patients have access to secondary prevention treatment and advice and that it is provided at a time when it is likely to be salient; iii) to standardise the content of secondary prevention advice so that it is evidence-based and less influenced by professional preferences or priorities; iv) to tailor the amount of advice provided to the patient and individualise the content so that it is personalised and relevant to the individual. The intervention not only fitted with the skills and priorities of the research team but also with current public health priorities targeting stroke and with recommendations in the new GP contract that general practices should keep chronic disease registers for their patients.<sup>320</sup> Figure 3 presents a diagram of the intervention process.

**Figure 3. The intervention process.**



The intervention process involves five key stages: (i) recruitment to the SLSR; (ii) data entry; (iii) transformation of data to intervention plans; (iv) distribution; (v) follow-up. Stage (i) involves identification of potential stroke patients through phoning ‘notification sources’, assessment by a clinical researcher to ascertain stroke diagnosis and collection of data on clinical, socio-demographic and health service factors relating to the stroke. Stage (ii) involves manually checking SLSR data collection forms for errors, entering SLSR data onto the computer and using computer processes to further crosscheck data for errors. Stage (iii) involves using computer algorithms to transform the SLSR data into individualised secondary prevention plans for patients, carers and the primary care team. The plans included details of the individual patient’s risk factors, together with evidence-based advice on appropriate management. Patient plans include instructions on what to do to improve secondary prevention and detailed advice on their own specific risk factors and treatments. GP plans included individualised information on their patients’ risk factors and the relevant RCP guidelines on best practice. Examples of patient and professional plans are presented in Appendix 7. In stage (iv) plans are distributed to patients and carers and the primary care team. In stage (v) patients are followed up at three and six months post stroke by the SLSR team to collect



additional data, develop and distribute new intervention plans to reinforce the messages delivered in the initial plan.

#### *7.3.4. Time and place for intervention delivery*

Ideally, to meet the recommendations of the theoretical phase, the intervention needed to be delivered at the time point most relevant to patients. Currently, secondary prevention appeared to be delivered when the patient was in hospital (at a time point close to when the acute event had occurred) but evidence from the theoretical phase suggested that this was not necessarily the most appropriate time or place<sup>ix</sup>. As discussed in Chapter 5, patients may have had other priorities at this time such as focusing on recovery and getting home. However, since the intervention was to be designed using the SLSR and the SLSR used designated (academic and practical) time points to collect information, it was not possible to collect data or deliver the intervention at a time point dictated by each individual patient.

The theoretical phase findings (from the literature review, patient interviews and clinic observations) also suggested that the time when such information was likely to be relevant to most patients was after discharge from hospital. While patients were in hospital they and their community health professionals had little control over secondary prevention strategies but on discharge, responsibility was shifted to the individual patient and to community services. It was hypothesised that if the intervention was delivered at multiple time points after discharge then one of these time points would hopefully be a relevant time for patients to focus on secondary prevention and to receive the information. Again, ideally to meet the recommendations of the theoretical phase,

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<sup>ix</sup> My own preliminary analysis of SLSR data suggested that only approximately 14% of patients reported receiving written advice about their stroke either because it had not been provided, or they could not remember receiving it, indicating that current methods of delivery were inadequate.

the intervention would have been designed to deliver secondary prevention plans on discharge and then at three months and six months post discharge. However, since the SLSR collected information at time points 'post stroke' rather than 'post discharge', the ideal delivery time points were modified so that the intervention was delivered at three and six months post stroke.

There was considerable debate within the Stop Stroke team about the most appropriate place to deliver the patient component of the intervention, whether to deliver it to the patient in hospital or to send a package to the patient's discharge address. The lead stroke clinician was keen that the intervention be delivered to patients in hospital so that health professionals could explain any information provided in the secondary prevention pack. He felt that this would add weight and credibility to any advice provided as well as allowing the professionals to monitor what advice their patients were being given. However, as an investigator I raised a number of concerns about hospital professionals being involved. Delivering the intervention in hospital conflicted with my own analysis from the theoretical phase, which suggested that any advice would be better provided after the patient had returned home. Equally, the intervention was to be evaluated in a RCT and I was concerned that since hospital staff would be treating patients in both arms of the trial, there was possibility for contamination of the control arm. I was also concerned that hospitalised patients in the intervention arm would receive a slightly different intervention: both a written package and counselling from health professionals; whilst non-admitted patients would receive only the written package. This did not seem consistent with RCT methods and might make it difficult to define the replicable components of the intervention. These concerns were discussed amongst the team who concluded that different methods of delivering the intervention should be investigated further in the exploratory trial.

The two alternative methods for delivering the intervention (in hospital versus postal delivery) were tested by the PHT responsible for the exploratory trial. Her testing revealed a number of practical problems in providing the intervention to patients in hospital. Firstly, it was difficult to predict exactly when patients were to be discharged from hospital, making it problematic to obtain the necessary information and deliver the intervention before the patient left. Some of the information such as ongoing medication was not prescribed until the point of discharge. For a combination of reasons, theoretical, methodological (relating to the RCT) and practical, the PHT recommended that all plans would be sent to the patient at their discharge address.

The influence of RCT methods had a further impact on the theoretical grounding of the intervention in March 2003 when the decision not to deliver the intervention to patients in hospital was reversed by the PI. With the current protocol, patients who had not been discharged from hospital at a given time point would not be eligible to receive the intervention package meaning that some patients would receive different 'doses' compared to others (if the patient had not been discharged at 6 weeks post stroke they and their GP would receive only two 'doses' of the intervention; if they had not been discharged by 3-months they would receive only one dose of the intervention and if they were still an inpatient at 6-months they would receive nothing). The PI felt that if some patients did not receive all three doses they would essentially be receiving a different intervention and thus it would be difficult to identify the active components when generalising the intervention elsewhere. To make the intervention more robust, he decided that it was necessary to deliver the intervention both to those still in hospital and those who had been discharged. In consultation with the SLSR field workers (clinical and non clinical) and statisticians, the core investigators decided on a six-week cut-off time point for intervention delivery, that is if the patient had not been discharged



from hospital within six weeks of their stroke, the intervention would be delivered to them in hospital. The six-week time point was chosen since the SLSR field workers felt that of those discharged from hospital, the majority were discharged within this time period.

#### **7.4. Developing intervention components**

Having decided on the intervention concept, the next stage involved developing individual components (data collection and data management methods, computerised system for transforming data into secondary prevention advice, patient and professional information, method of delivery). As noted in Chapter 1, in 2000 the RCP published evidence-based guidelines on best practice in stroke management.<sup>27,33</sup> The guidelines included a section on secondary prevention outlining the key risk factors and treatments for those risk factors. The guidelines were primarily targeted at health professionals but also included a 'lay' section designed for patients. The PI suggested that these should be used to guide the different aspects of patient and GP intervention components, that is to guide decisions about what constitutes appropriate secondary prevention and what advice should be provided to patients and professionals.

Three main tasks were required in designing the intervention components: i) development of computer algorithms to evaluate individual patient data and define appropriate steps for management, ii) adaptation of the SLSR to collect and process data, iii) development of patient and professional information literature.

In the original proposal, in addition to the secondary prevention plans, academic detailing visits by stroke experts had been included as one of the intervention components. There was some evidence from the literature that education provided by clinical specialists could influence GP prescribing behaviour, particularly when coupled

with social marketing strategies.<sup>319</sup> The nature of these visits was not clearly defined but academic detailing has been defined in the literature as educational outreach visits to providers in their own setting (for example the GP practice).<sup>319</sup> In the Stop Stroke intervention the detailing component involved a member of the team (the PI, lead stroke physician or junior doctor) visiting GP practices in the intervention arm. These visits were used for multiple purposes including: introducing the intervention; introducing the new RCP guidelines; providing information about the SLSR; and about local stroke services including the recently developed neurovascular (or TIA) clinic.

#### *7.4.1. Developing a computerised method of transforming SLSR data into individualised advice*

As previously discussed, initially the investigators considered linking in the current intervention with previous attempts at ‘computerising’ chronic disease management such as Diabeta-3<sup>318</sup> (a new computer software package for GPs to enable them to monitor diabetes risk factors). However, since the SLSR and most GP practices were already computerised we (the investigators) felt that the computerised system for Stop Stroke needed to utilise these existing systems rather than create new ones. I proposed using current data and analysis software for the SLSR (Epidata, Microsoft Excel and STATA) to input patient data and evaluate patient’s secondary prevention. This would then be linked to a word processing package such as Microsoft word), which would be used to produce patient and professional secondary prevention plans using the ‘mail merge’ facility.

In July 2001 I drafted a proposal for the development of a computer system to turn SLSR data into hard/electronic copy secondary prevention plans (Appendix 8). I had experimented with the SLSR dataset used previously to examine socio-demographic

patterns in behavioural risk factor management in the theoretical phase and found a method of combining SLSR data with a cover letter (using the word processing mail merge facility) to produce an individualised plan. My initial estimated timeframe for development was four months. In practice, although this initial design was completed within the time frame, the final computer system for the intervention took a further year and a half to complete and needed ongoing refining once the intervention was implemented.

The computer system used SLSR data exported from EpiData (a data entry software package) and read into STATA (a statistical package) for analysis. A series of data checks were designed to take place before the analysis started. These included checking serial numbers, dates of birth and dates of stroke from different files, to ensure that data from each file were merged for the correct patient. Commands were also designed to conduct preliminary data cleaning (to check dates and ages to ensure they were within range; to recode missing data). Finally when all the data were 'clean' the computer system used a series of algorithms to define and analyse the patient's risk factors, to produce statements about their current secondary prevention management and to generate instructions for patients on how to improve management. The algorithms worked by sequentially examining SLSR data for each risk factor and each patient to calculate whether the patient had the risk factor and if so how well it was being controlled. Initially a decision was made to focus on the patient's three most important risk factors. The lead stroke physician suggested that patients might become overburdened with information if they were given information on more than three risk factors and certain risk factors (high blood pressure, diabetes) were felt to be more important than others (lack of exercise, diet). However, once testing of the intervention started, it became clear that many patients had more than three risk factors for which



they were receiving treatment. I was concerned that patients might become confused if references to stroke medication did not include all their treatments. By limiting the advice to only three risk factors some important risk factors might be excluded (for instance a patient might have atrial fibrillation, diabetes and hypertension in which case their smoking behaviour would not be discussed). The investigators agreed and subsequently the algorithms were redesigned to produce information on all risk factors. The computer algorithms were designed using the RCP evidence based guidelines and expert consensus. The definitions of risk factors derived from these sources are presented in Table 11.

Patient information on stroke type and risk factors was designed to provide a definition of the risk factor and an explanation of the relationship between having the risk factor and strokes. For those without clinically defined high levels of blood pressure or cholesterol, alternative information was designed explaining relationships between blood pressure or cholesterol and stroke.

#### *7.4.2. Defining appropriate management and instructions for patients*

The aim of treatment advice was to provide patients with statements on management relevant to their own risk factors but standardised across patients with the same risk factors. Although evidence based guidelines were used to help define appropriate risk factor control, guidelines alone were not sufficient to define patient instruction. In some cases recommendations were too ambiguous or were unable to answer the questions patients had raised as being important to them (for example failing to define terms such as ‘heavy’ drinking or ‘healthy’ diets). There was a lack of consensus amongst authors of different guidelines as to which risk factors needed to be targeted for optimal secondary prevention (not all included alcohol use as a risk factor and different

**Table 11. Risk factor definitions used in computer algorithms.**

Risk Factor	Diagnosis
Hypertension:	Patients were considered hypertensive if they had a diagnosis of hypertension prior to stroke, if they had a previously recorded blood pressure of >140/85, if they were diagnosed with hypertension in the 6 months post stroke or if their blood pressure measured at 3 months and 6 months post stroke was >160/85. Patients not diagnosed as hypertensive were considered to have 'normal' blood pressure even if they were prescribed blood pressure lowering medication.
Atrial Fibrillation:	Atrial fibrillation was diagnosed if an ECG confirmed that they were in atrial fibrillation at the time of stroke or if they had a diagnosis of atrial fibrillation in the first 6 months post stroke
Diabetes:	Patients were diagnosed as diabetic if they had a recorded history of diabetes prior to the stroke or were subsequently diagnosed with diabetes whilst in hospital or within the first 6 months of stroke
High cholesterol:	Patients were diagnosed with high cholesterol if they had a recorded cholesterol of >5mmL prior to stroke or a previous history of high cholesterol, or if they were diagnosed in the first 6 months post stroke. Patients not defined as having high cholesterol were considered to have 'normal' cholesterol even if they were prescribed cholesterol-lowering medication.
Smoking:	Patients were diagnosed as smokers if they were smokers at the time of stroke or reported smoking any tobacco, cigarettes or cigars within 6 months of the stroke
Heavy alcohol use:	Patients were diagnosed as drinking heavily if their total weekly alcohol consumption at the time of stroke or in the first 6 months post stroke was greater than 28 units or alcohol a week for men or 21 units a week for women.
Obesity:	Patients were diagnosed as being obese if their body mass index (BMI) was greater than 30 at the time of stroke or within the first 3 months post stroke.
Stroke type:	The patient's stroke type was confirmed by a CT scan at the time of stroke. Patients were divided into two types, ischaemic and haemorrhagic strokes.

guidelines included different levels of blood pressure requiring treatment). Some of the evidence underpinning the recommendations came from studies of primary stroke prevention rather than secondary prevention<sup>33</sup> and it was assumed that the findings could be transferred (for example that exercise, diet, weight loss, smoking cessation and reduction of added salt would be beneficial even *after* a stroke to prevent a recurrence). Recommendations also changed quite dramatically in the early stages of development with new evidence emerging on the appropriateness of different medications (in

particular HOPE, PROGRESS and The Heart protection Study looking at the efficacy of antihypertensive and lipid lowering drugs for those without particularly high levels of blood pressure or cholesterol<sup>321-323</sup>).

Table 12 lists the different risk factors prioritised in four different guidelines: The RCP;<sup>33</sup> the European Stroke Initiative Guidelines (ESI); the National Service Framework for Older People (NSF)<sup>26</sup> and the British Hypertension Society Guidelines (BHS).<sup>324</sup>

**Table 12. Risk Factors Prioritised in 4 different Evidence Based Guidelines.**

Risk factors included	Guidelines			
Antiplatelet therapy	RCP	ESI		BHS
Anticoagulants for atrial fibrillation	RCP	ESI	NSF	
Hypertension management	RCP	ESI	NSF	BHS
Smoking cessation	RCP	ESI	NSF	BHS
Diabetes		ESI	NSF	BHS
High cholesterol	RCP	ESI	NSF	BHS
Alcohol Use	RCP	ESI	NSF	BHS
Obesity	RCP		NSF	BHS
Diet	RCP		NSF	BHS
Exercise	RCP	ESI	NSF	BHS

RCP: Royal College of Physicians  
ESI: European Stroke Initiative  
NSF: National Service Framework for Older People  
BHS: British Hypertension Society

In order to clarify these inconsistencies, I gave a short questionnaire to six clinicians with a special interest in stroke to gain a consensus of opinion. Questions included: how should appropriateness for medications be defined and what are the contraindications



for medication? How should hypertension and high cholesterol be defined? Are pipe/cigar smoking risk factors? How should alcohol use be measured and how is heavy drinking defined? How should obesity, poor diet and physical activity/inactivity be defined and what advice should people with these risk factors be given? Their answers were varied and there was no clear consensus over what advice should be provided to help patients with diet, exercise or losing weight. For example, one doctor simply suggested “eat less and do more exercise” to lose weight. Where no clear consensus was achieved, I developed definitions in consultation with I1 using a combination of the clinicians’ responses, published evidence, health promotion advice and government recommendations.

Risk factor treatment was categorised into three types, surgical, medicinal and lifestyle. Some risk factors such as hypertension could be treated either with medication or through lifestyle intervention (such as dietary change) or using a combination of both. Surgical interventions were not included, the focus being on the main lifestyle and medicinal interventions (blood pressure lowering, cholesterol lowering, smoking cessation, diabetes management, alcohol moderation, use of antithrombotics, diet and exercise). Definitions of those appropriate for the intervention and appropriate advice are given in Tables 13 and 14.

In developing instructions for patients, as an intervention developer, I felt that it was important to allow for the possibility that the information collected was incomplete or inaccurate. The algorithms were designed to standardise patient information but certain patients might be unusual and not fit the appropriateness criteria. Therefore statements were designed so that patients were recommended to continue with their current

Table 13. Medicinal interventions.

Intervention	Target group	Advice provided
Antihypertensives.	Patients with or without a history of hypertension were considered appropriate for antihypertensive medication.	<p>Patients prescribed antihypertensives were sent information about their medication at the time of stroke. This information was repeated at 3 and 6 months if patients were experiencing problems with their medication or if they requested further information.</p> <p>If the patients' blood pressure was not controlled (they were diagnosed as hypertensive or had a blood pressure reading &gt;140/85) and they were not taking medication, or if they had not had a blood pressure check since the stroke they were instructed to see their doctor.</p>
Warfarin.	Ischaemic stroke patients with atrial fibrillation and no contraindications (stomach ulcer, cancer, recent operation, gastrointestinal bleed) were considered appropriate for warfarin. It was recognised that some patients without atrial fibrillation might also be appropriate for warfarin and conversely that not all patients with atrial fibrillation would be prescribed it.	Patients prescribed warfarin were sent information on warfarin at the time of stroke. This information was repeated at three and six months if patients were experiencing problems with their medication or if they requested further information. Patients considered appropriate for warfarin but not prescribed it and those with contraindications to warfarin who were taking it, were instructed to see their doctor to confirm they were taking the right medication.
Aspirin.	Ischaemic stroke patients not taking warfarin and with no contraindications (aspirin intolerance, ulcer) were considered appropriate for aspirin. However in some cases it was recognised that patients may be taking both aspirin and warfarin.	Patients prescribed aspirin alone were provided with information on aspirin at the time of stroke. This information was repeated at three and six months if the patient was having problems with their medication or if they requested further information. Patients considered appropriate for aspirin not taking it were instructed to visit their doctor to check they were on the right medication.

Intervention	Target group	Advice provided
Clopidogrel or dipyridamole.	Ischaemic stroke patients not taking warfarin and with no contraindications (ulcer) were considered appropriate for alternative antiplatelets. It was possible for patients to take both aspirin and a second antiplatelet such as dipyridamole or to take only the alternative. Taking aspirin prior to the stroke was considered an indicator for the patient to take clopidogrel or dipyramole in combination with aspirin after the stroke.	Patients prescribed clopidogrel or dipyridamole (either alone or in combination with aspirin) were provided with information on antiplatelet medications at the time of stroke. This information was repeated at three and six months if patients were experiencing problems with their medication or if they requested further information. Patients considered appropriate for antiplatelets other than aspirin but who were not prescribed them were instructed to visit their doctor to check they were on the right medication.
Insulin & Oral hypoglycaemics.	Patients prescribed medication for diabetes were considered appropriate for medication.	Patients prescribed insulin or oral hypoglycaemics at the time of stroke were sent information on diabetes medication. This information was repeated at three and six months if patients were experiencing problems with their medication or if they requested further information. Patients controlling their diabetes with their diet were not instructed to see their doctor about medication.
Statins.	Patients with and without a diagnosis of high cholesterol were considered appropriate for statins.	Patients prescribed statins were sent information on their medication at the time of stroke. This was repeated at three and six months if patients were experiencing problems with their medication or if they requested further information. Patients with a diagnosis of high cholesterol and not on medication and those with a cholesterol measure >5.0mmol/L were instructed to see their doctor to check whether they were taking the right medication. Patients who had not had a cholesterol check since the stroke were advised to see their doctor.



Table 14. Lifestyle interventions.

Intervention	Target group	Advice provided
Diet.	All patients were considered appropriate for advice on diet after the stroke.	Diet information was linked to advice on blood pressure, cholesterol, obesity and diabetes and sent to anyone who was not controlling these risk factors or who had not tried modifying their diet (cutting down on salt or fatty foods) since the stroke. Diabetic patients were given special advice on diabetes and diet.
Exercise.	All patients were considered appropriate for advice on exercise after stroke.	Exercise information was linked to obesity and sent to anyone diagnosed as obese who had not tried increasing exercise since the stroke.
Smoking cessation.	All smokers were considered appropriate for smoking cessation advice.	Smokers were instructed to give up smoking and sent advice on cessation unless they indicated that they had successfully quit.
Reduction in alcohol use.	All patients defined as 'heavy drinkers' were considered appropriate for alcohol advice.	Heavy drinkers were instructed to cut down on the amount they drank. Men and women received different advice on appropriate alcohol use since evidence based optimal drinking levels differed for men and women. Instructions were provided at the time of stroke, 3 and 6 months post stroke unless the patient had cut down on to 'moderate' alcohol use.

treatment regime unless problems were identified, in which case they were recommended to visit their doctor for a check up. Patients were not recommended to stop their treatment even if (according to the algorithms) the treatments appeared to be inappropriate. In such cases the primary care plan would alert the GP if medication was thought to be contraindicated.

Having defined patients' risk factors and produced statements on appropriate management, computer programmes were designed to merge the SLSR data with patients' names and addresses. Prior to merging, patients' personal details such as name and address were stored separately from clinical data at all times and only merged with the clinical data to produce the hard copy plans. This ensured data protection requirements were fulfilled. The merged data were then imported into a Microsoft Word mail merge letter template. Each exported variable formed a 'field' in the letter template or was used to create a text statement giving particular instructions. Thus individual patient data was slotted into standard letters and tables.

With the system for producing individualised secondary prevention plans now computerised, in theory intervention distribution needed only administrative skills to enter the data, process the algorithms, print off the finished plans and post/deliver them to patients and professionals.

## **7.5 Adaptation of the SLSR**

The original aim of the SLSR was to collect stroke incidence data in a defined area of south London and to collect clinical, socio-demographic and health service data for clinical and social research studies within the team. However, for the purposes of the intervention some of the SLSR processes were not sufficient. Additional questions needed to be designed to enable collection of specific risk factor data (for example

questions on behavioural risk factors such as smoking, alcohol use and diet needed to be added). A completely new data collection time point (the six-month follow-up) needed to be put in place and the procedures for collecting and managing data needed to be revised, all without impacting on the existing data collection for the SLSR since it and its dependent projects were research studies in their own right.

One of the key challenges for adapting the SLSR was addressing the timeframe for data collection and analysis. Existing time frames were relatively flexible (for example data did not need to be entered onto the computer until it was needed for analysis at a later date and a batch system was in operation for doing this). However, for the purposes of the intervention, data collection and analysis processes needed to be 'real-time'. In the first stages of development, the intervention was designed using a separate data entry system. The intervention needed to use only a fraction of the total data collected by the SLSR and having a separate data entry system speeded up data processing and made data cleaning a simpler task. It was this system that was tested in the exploratory trial phase described in the next section. However, in January 2003 the PI proposed that data entry and processing should be carried out using existing SLSR data entry processes. He felt that a separate intervention data entry system was not practical (since some SLSR processes such as data entry would be duplicated) and that using existing processes would make the intervention more generalisable to other chronic disease registers.

I held discussions with the SLSR statistician and the TC to investigate the possibility of using the SLSR data entry system. The conclusion was that making SLSR data entry 'real time' was not possible. The SLSR protocols and practices had developed over nearly eight years and the team met proposals to change established practices with resistance. As the sole person responsible for creating the computerised component of the intervention, I also resisted this decision. The programmes already developed would



need to be considerably changed to operate with an alternative data entry system but this aside, changing the system meant that responsibility and control over the data would be passed from the smaller Stop Stroke research team to all those involved in data collection and processing for the SLSR. This increased the potential for error. To illustrate the advantages and disadvantages associated with each method I made a list with the aim of convincing the investigators and the SLSR staff that that the disadvantages of merging data collection outweighed the advantages (Table 15).

**Table 15. Advantages and disadvantages of using established SLSR protocols to process data.**

	Separate data entry	Combined data entry
<b>Advantages:</b>	<p>Tidy and less room for error.</p> <p>Ready to implement.</p> <p>Is independent of future changes made to SLSR systems.</p> <p>Does not require stats support.</p>	<p>Speeds up the SLSR data entry system – improvements for other studies.</p> <p>Does not require specific data entry person for Stop Stroke</p>
<b>Disadvantages:</b>	<p>Data are entered twice.</p> <p>Some SLSR data required for the intervention were not currently entered onto the SLSR.</p> <p>Requires a person on the SLSR to take specific responsibility for Stop Stroke.</p>	<p>Requires a dedicated real-time data entry person.</p> <p>If a backlog of data entry occurs the intervention will fail.</p> <p>Data will need to be entered at many time points.</p> <p>Data entry is “messy” – more room for error.</p> <p>Stop Stroke programmes need to be re-written.</p>

Three systems were proposed: system one involved separating data entry for the SLSR and for the intervention; system two involved combining data entry for the two systems; and system three involved a combination of separate data entry for the initial time point (when turnaround is most urgent) and combined data entry for the follow-up time points. The main advantages of the combined system appeared to be the overall

improvements this would have for studies linked to the SLSR and the lack of replication in duties between studies. The main disadvantages were the potential for loss of ownership, lack of clarity of responsibilities for different studies and problems with existing systems such as the current backlog in data entry. In reflecting on my own agenda, it is also important to note that having developed a functioning intervention, I felt protective over Stop Stroke and did not want to lose ownership or see the problems associated with managing larger SLSR processes affecting the efficacy of the intervention. However, at the next meeting in February 2003 the decision to use only the SLSR data entry system had been finalised by the PI and other SLSR members and I never found the opportunity for proposing the alternatives.

To address some of the difficulties in adapting existing data management processes to meet the needs of the intervention, JS2 proposed splitting the data collection form for the initial data collection (the most difficult form to complete and return in the designated time frame) into four sections so that the data needed for the trial (in the first three sections of the form) could be prioritised and so that data which were difficult to collect quickly (such as test results not relevant to the intervention) would not delay data processing.

## **7.6. Developing patient and professional information literature**

### *7.6.1. Professional information literature*

Although the professional secondary prevention plan was sent to the patient's GP, the aim was for the information to be made available to all members of the primary care team (since many practice nurse or other practitioners involved in health promotion might take responsibility for secondary prevention). The trial steering group stressed the

importance of focusing on the team as a whole and not just the GP. A covering letter accompanied the intervention package explaining what the pack included and who it was for. It encouraged GPs to file the patient information with practice data on the patient. The professional intervention (Appendix 7) consisted of a single page plan with a table listing stroke type and the six main risk factors for stroke (hypertension, atrial fibrillation, diabetes, high cholesterol, smoking, heavy alcohol use and obesity). At each time point the individual patient's risk factor status, test results and pharmaceutical management were inserted together with any contraindications to treatment and patients' reported attempts to change risk factors (such as attempts to lose weight or give up smoking). Individual patient data were located next to the relevant RCP guidelines on stroke secondary prevention (for example patient's hypertension status, last recorded blood pressure result and antihypertensive medication prescribed were positioned next to the guideline on managing blood pressure). The PI had met with a manager at the local PCT who had recommended we incorporate GP read codes (codes compatible with diagnosis used in current practice software) into the package so that GPs could easily transfer the information to their own computerised databases. Where appropriate, GP read codes were inserted next to risk factors and treatments. For non-computerised practices the single sided sheet was designed so that it could be folded and stored in the patient's notes. Both patient and professional plans were printed on coloured paper, yellow at the initial time point, green for the three-month time point and peach for the six-month time point. This was so that the plans would stand out, also hopefully to encourage recipients to see that each plan was different.



### *7.6.2. Patient information literature*

The patient information literature was developed by Il and me, drawing on findings from the theoretical phase and the RCP professional guidelines (in practice the RCP lay guidelines were not detailed enough to develop information literature). The aim was to develop information that would be evidence based but also, would: a) address the needs of patients; b) be tailored to the individual patient; and c) be accessible. Development of the patient plans was more complicated than the professional plan since it was expected that there would be more diversity in patients' baseline understanding of stroke secondary prevention. The intervention needed to provide enough information to satisfy those who wanted to know about their risk factors in detail but without being too technical for a non-clinical person to understand.

Il and I decided that in order to provide enough detailed information, patient advice would be provided in two parts, an individualised part (single page letter containing a table detailing the individual patients' risk factors, Appendix 7) and a standardised part (a series of numbered information sheets containing more detailed information on specific risk factors and management strategies, Appendix 9). However, even with the standardised information, each patient would receive only the sheets relevant to their individual risk factors.

Content of the individualised plan included diagnosis of risk factors, test results, summary of previous and current management and tailored instructions on how to improve preventive management. The plan also referenced the relevant information sheet numbers so that patients would know where to find additional information.

Twenty-one standardised information sheets were developed in total covering stroke type and the six main risk factors and their management. With changing evidence on the

appropriateness of pharmacological treatments the system needed to be able to adapt to changes in best practice (for example sheets on blood pressure and cholesterol for those without hypertension or hypercholesterolaemia were introduced just prior to the start of the trial). Five sheets focused on the pharmacological management of future stroke risk: aspirin; dipyridamole and clopidogrel; warfarin; blood pressure lowering medication; and cholesterol lowering medication. Six sheets were designed focusing on lifestyle management: diet for non-diabetics; diet for diabetics; exercise; smoking cessation; and separate alcohol use sheets for men and women. We aimed to make each sheet a maximum of two sides of A5, which would be laminated to protect it from wear and tear and to encourage patients not to throw it away. Readability of patient information literature was an important consideration in the design of the sheets. It was hypothesised that readability would be influenced by a number of factors including format, layout, organization, font size and use of graphics.<sup>325</sup> Guidelines were followed to design the format and style of the information incorporating pictures, using text boxes and headings to break up the text.<sup>326</sup> Since the average age of stroke patients is 70 years and many older people have difficulties with sight, attention was focused on text size. Consequently, all sheets were designed with text no smaller than Arial size 16 so that even those with some sight difficulty would be able to see the text.

The reading level of the patient information was tested using a SMOG test (simple measure of gobbledygook<sup>327</sup>) by the public health trainee (PHT). The test focused on sentence length and number of syllables per word to calculate the average reading age at which the information is pitched. Having tested the literature, Il and I subsequently reworded sections to decrease the reading level to a maximum reading age of an 11 year-old. We found it particularly difficult to discuss clinical risk factors such as atrial fibrillation and hypertension, which have many syllables without increasing the reading

level of the information. However, we felt it important that these technical terms were explained. All information sheets were checked by the lead stroke clinician before being distributed to patients in the exploratory trial.

### **7.7. The Exploratory trial and revising the intervention.**

The MRC Framework is quite flexible about what the exploratory trial should entail but in the case of the Stop Stroke intervention this phase was not clearly demarcated from the modelling phase. However, testing of the intervention components was conducted by the PHT and involved 25 patients recruited to the SLSR and their GPs. Patients were not randomised and the focus was on testing trial procedures and gaining feedback on the patient and professional information literature rather than trial outcomes. To test the intervention using the main trial outcomes would have required a further year of data collection, delaying the start of the trial further. Instead a qualitative evaluation was conducted.

The MRC framework emphasises that qualitative methods can be used in the modelling phases but qualitative methods are not discussed in relation to the other phases of development. However, Patton argues for the use of qualitative methods at all stages of programme development, particularly during implementation.<sup>95</sup> In the Stop Stroke exploratory trial, patients and their primary care professionals were interviewed two weeks after the intervention was delivered to find out whether they had received the intervention, what they had understood from the advice provided and what actions they had taken as a result of the advice. GPs and other health professionals were very positive about the intervention but a number of problems were identified with the patient information literature. One of the key aims of the intervention package had been to try to make the approach to secondary prevention delivery more representative of a



chronic disease rather than an acute event. Another was to make secondary prevention messages more relevant to the individual. However, it was clear from the pilot that in its current format the intervention might fail at the first hurdle since patients were not clear that advice was individualised and subsequently disregarded it. The 'packaging' of the intervention needed additional input and it was decided to present the intervention to patients in a plastic wallet with a sticker on the front identifying the patient. This was designed to encourage patients to keep their package and return to it if they had questions about secondary prevention in the future.

In November 2002, feedback was also sought from the South London Stroke Patient Forum, a group the stroke team were trying to form to provide patient input on stroke research. However, only three patients attended the meeting. The RA gained additional feedback from patients after presenting the packs during her routine SLSR visits. In some cases changes recommended by professionals (such as removing the numbering system to link statements on risk factor management in the individualised plan to the more detailed standardised advice sheets) conflicted with patients' suggestions or requests for information identified in the theoretical phase. In such cases patient feedback rather than professional feedback was used to inform design.

Having revised the sheets it was decided that they would be presented to the entire stroke team at the team's journal club meeting (March 2003) for a final chance for members of the team to give feedback. The meeting started with the lead stroke clinician (who had previously approved the sheets) disagreeing with content and asking whether he had ever seen the sheets before. The sheets had changed since his original viewing but not substantially and he had also been through the content in great detail at the patient forum four months previously. Lack of consensus again emerged between different health professionals over the most appropriate way to define risks and provide

explanations (I2 and SPR4). It also appeared to be difficult to reconcile differences between the patients' perspective (answering their questions and acknowledging their experiences) and the need to provide information that the clinicians felt was clinically accurate. For example, I2 was unhappy about acknowledging that patients might experience symptoms of high blood pressure arguing that there was no clear evidence of symptoms in the clinical literature. In addition, there was tension between recommendations in the literature to provide an honest account of what is and what is not clinically well understood (for example acknowledging where epidemiological evidence is lacking)<sup>328</sup> and the professional need to maintain their status as experts. I2 also queried the statement 'no one knows why you had your stroke' (which was aimed at acknowledging that few strokes have a direct cause or event that led to their stroke on a particular day or time). He argued that in most cases clinicians did know why the patients had had a stroke and that the statement might encourage a view that health professionals don't know what they are talking about.

The patient information sheets were revised again and the final stage of development was to present them at the steering group in April 2003 prior to the start of the trial. The steering group was positive about the intervention and the processes leading to its development but had concerns about patients with literacy problems, or those with speech and language difficulties. It was suggested that a question could be added to the SLSR to establish the patient's literacy level. If the patient had difficulty with reading then it was suggested that the information could be provided in an alternative form such as a video. However, the core investigators and I were unhappy with this suggestion since it was not something previously considered and would have involved considerable additional development and testing. Instead the team proposed that the SLSR researchers ask the patient to nominate a carer to whom the information could be sent if

the patient had communication difficulties. It was felt that those with language difficulties would most likely be reliant on a person (such as a friend or relative) who did not have language difficulties. The speech and language specialist felt that more could be done to design the information sheets for people with speech and language difficulties and offered to discuss them with her team. Unfortunately due to time constraints her team did not get involved in revising the sheets. Instead, ideas from the UK Connect<sup>x</sup> website were incorporated, for example highlighting key words in the text so that the main messages could be understood through key words and diagrams without having to read a full paragraph. No further evaluation was conducted prior to the start of the trial in July 2003.

## **7.8. Discussion**

As Patton stresses “Once in operation, innovative programs are often changed as practitioners learn what works and what does not, as they experiment and as they develop and change their priorities” (p19).<sup>95</sup> Analysis of the development of the Stop Stroke intervention illustrates how a protocol to design a theoretically driven intervention changed and evolved during the development process.

On numerous occasions the MRC Framework has been cited as having guided Stop Stroke intervention development but these data suggest that this was not strictly the case, since the research process for developing and evaluating Stop Stroke development were defined before The Framework was published. However, in many ways the multiple-stage research and development process outlined by the researchers in the original protocol does follow the recommendations for intervention development

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<sup>x</sup> UK Connect is a charity for people with speech and language difficulties. A number of staff working for UK Connect have particular experience in developing tools for communicating.



outlined in The Framework (use of literature review and empirical study to understand intervention process). Thus Stop Stroke intervention development can be regarded as an example of its application even if the theoretical phase research and evaluation design were not specifically guided by it.

#### *7.8.1. Putting theory into practice*

Although the MRC Framework suggests that demarcating a distinct theoretical phase, will lead to a more theoretically grounded intervention (and therefore a more efficacious intervention), in practice the theoretical phase of intervention development was used as much to justify research team ideas, as it was to guide them. Since the final intervention was only partially influenced by theory it raises questions about the ability of models such as The Framework to influence the theoretical grounding of interventions.

It was certainly our intention as investigators to develop a theoretically driven intervention and the theoretical phase findings did contribute in some ways to intervention design. However, in order to be truly theoretically grounded, the intervention would have needed to be based on a full analysis of the theoretical phase data. In the context of Stop Stroke this was not possible given the time and resource limitations but it is also questionable whether a lengthy theoretical phase would be appropriate. In the Stop Stroke study, the iterative process of progressing from theoretical to definitive RCT phases took approximately four years, requiring multiple sources of funding. Yet, even if a full analysis had been conducted, the intervention might still have reflected the research interests of the team over and above any theoretical recommendations. To ensure that interventions are theoretically grounded, Eccles et al., have recently published recommendations for choosing the most appropriate theory in intervention development.<sup>329,330</sup> However, like the Framework,

including such recommendations assumes that interventions can and should be influenced solely by theory. They do not allow for the practicalities of research or the ‘interference’ of extraneous factors such as resources, time, or investigator priorities. Such factors had an important impact in Stop Stroke intervention development.

In the case of Stop Stroke, designing an intervention that fitted in with the ongoing SLSR was probably the most important influence on intervention design. Given the expertise in the stroke team, the intervention was never going to be designed to tackle particular aspects of secondary prevention, such as the social problems of secondary prevention management highlighted in the theoretical phase findings (for example fear of crime or poverty). Designing an intervention to utilise the SLSR would not only potentially support ongoing research projects but would also fit with broader academic requirements to develop an area of expertise for academic assessment and to attract funding. Thus intervention design was also influenced by the broader political academic context within which health and social care research is situated.

Having defined the intervention concept, the actual components were further influenced by practical and resource issues. Since the SLSR was already established, redesigning it so that assessments would fit in with service changes rather than the natural history of stroke would have required additional resources. In some cases the intervention design also appeared to be influenced by medical hierarchies and authority. Clinicians and other investigators (members of the advisory group) made or requested changes to intervention components to support their own agendas and maintain their authority as experts despite the intervention being based on evidence from patient interviews.

I have termed such influence ‘interference’, in other words things which interfere with theoretical purity. When I first presented these findings (at the Society for Social Medicine and to the PI) I was criticised for using the term interference, since it was

argued that these findings simply reflect the difficulties of real life research and thus are of little interest. However, I would argue that such criticisms support rather than negate the argument. In the case of Stop Stroke, despite attempts to base the intervention on qualitative research evidence, the intervention was not theoretically pure. If such interference is an inevitable part of the process in developing complex interventions (in other words it is not possible to operationalise theoretical recommendations<sup>331,332</sup>) then MRC Framework recommendations to develop theoretically based interventions using extensive theoretical phases seem unrealistic. Others have reported similar conflicts in multi-disciplinary research and similar challenges for integrating ethnographic or qualitative research findings in generating knowledge of health and health services.<sup>82,89</sup> In the case of Stop Stroke, interference in the form of political, practical and resource influences may be as important as the underlying theoretical work in understanding the success or failure of the intervention.<sup>100,333</sup>

#### *7.8.2. Challenges of the exploratory trial phase*

The MRC Framework also recommends the use of an exploratory trial to pilot the intervention prior to the main RCT. However, it is not clear in the context of complex interventions how this phase should be operationalised. The Framework is not intended to be prescriptive but does suggest questions to be addressed in this phase including investigating variations in the intervention components and methods of delivery, ensuring that intervention delivery is standardised, investigating the comparative arm and investigating sample size.<sup>1</sup> In the Stop Stroke pilot evaluation, only one of these questions, variations in intervention delivery was investigated. The phase was used for testing the feasibility of delivering the intervention rather than for testing outcomes and the impact of the intervention was tested using qualitative methods, something not



recommended by The Framework. The pilot evaluation resulted in substantial revisions to the intervention. However, following these revisions a second pilot was not conducted, so that the intervention in its current form was not tested prior to implementation. It is not possible to ascertain whether the interpretation of the exploratory trial used in the Stop Stroke study has had an influence on intervention efficacy, since complex interventions by nature are likely to be difficult to evaluate because the whole is often greater than the sum of the components.<sup>7,334</sup> The Stop Stroke intervention needed to be able to change over time; it also needed to be reactive to new research findings and therefore it was not possible to pre-test all aspects of the intervention prior to implementation. The exploratory trial phase in The Framework appears to isolate the intervention components from the context within which they are delivered. Thus it ignores the difficulties of piloting complex interventions, assuming that the environment and components remain static once tested. This was not the case, nor could it have been for the Stop Stroke intervention, which was designed to be both tailored to the individual and able to accommodate changing best practice guidelines.

### *7.8.3. The influence of RCT design*

Finally, intervention design also appeared to be influenced by the chosen evaluation methods. Since the MRC Framework required that the intervention be evaluated for efficacy in a RCT, it needed to be a concept or entity, which could be subjected to the rules of RCT design. In some ways these rules (or our interpretation of the rules) restricted the intervention design. In particular, the assumption that all patients should receive an identical intervention interfered with the intervention design. While the theoretical and exploratory trial phases suggested that it would be difficult to implement an intervention delivered to patients in hospital and these patients might be less likely to

benefit from it, at the last minute, decisions were made to deliver the intervention to these patients. Equally, concerns about randomisation and contamination of trial arms may have limited the intervention in a way that could influence its future uptake.

These findings also raise broader questions about the nature of scientific evidence for complex interventions. If intervention choice is influenced by interference from the research team or by evaluation design then this may also limit the sorts of intervention that will be developed. For example, it may encourage development of interventions which are more easily evaluated using RCT methods, or those that fit within a given research budget but have little chance of influencing health outcomes.

#### *7.8.4 Implications for understanding trial outcomes*

One of the key assumptions of the MRC Framework is that if the intervention is informed by theoretical work, then it will help in interpreting eventual trial outcomes (whether positive or negative) and will thus help when generalising the intervention outside of the trial context. However, if social, economic and political forces interfere with the theoretical purity of intervention design then it makes it more difficult to interpret trial outcomes. For example, if the intervention is unsuccessful it will be difficult to untangle whether this is due to failed theory, inappropriate use of theory or interference from elsewhere. This in turn makes it difficult for others to learn from and build on trial findings.

The implications of these findings for complex intervention development are discussed further in Chapter 10. In the next two chapters I investigate intervention delivery in the Stop Stroke Trial itself, how the intervention is implemented and the impact it has on patients' experiences of secondary prevention.

## **Chapter 8. The Stop Stroke Trial.**

Following on from the previous chapter, in this chapter I present findings from the process evaluation of the Stop Stroke definitive RCT. The chapter focuses on implementation of the intervention within the RCT setting. The process evaluation was embedded within the RCT to help in understanding the eventual success or failure of the intervention.

### **8.1. Good practice in conducting RCTs**

While there is some guidance on the best way to develop complex health interventions, as argued in Chapter 2, there is less published guidance on the best way to conduct a RCT of such interventions. However, there are recommendations for good practice in conducting clinical trials of pharmacological interventions that cover organisation, planning and monitoring. Such recommendations include details of the responsibilities of the host institution, the principal investigator, other investigators and those of independent committees (steering committee, data monitoring committee).<sup>65,335-337</sup>

Common recommendations include: that the study has a clearly defined protocol; that staff understand the requirements of the protocol; and that staff ensure that participants have given informed consent. It is recommended that a trial coordinator be nominated and that staff have sufficient expertise to carry out their duties. The recommendations outline the responsibilities of independent committees including ensuring the trial sticks to the original protocol, ensuring recruitment is sufficient and that the intervention is safe to use. However, these recommendations were developed for more traditional clinical trials and little is known about their application to trials of complex interventions.



## **8.2. Evaluating the Stop Stroke Trial**

As in the previous chapter, I used an ethnographic approach to explore intervention implementation. I used a range of quantitative and qualitative methods to record data and analyse trial processes (see Chapter 4, section 4.5 for a detailed description of the methods). The analysis presented in this chapter covers the first two years of the trial, which started on 21<sup>st</sup> July 2003. Data used to illustrate the problems of trial conduct and intervention implementation are verbatim quotes from research staff and extracts from my own trial diary unless otherwise stated. Details that might identify staff have been changed to protect their identities.

## **8.3. The evaluation team**

Participants in the RCT included many of those involved in the development of the intervention (Chapter 7) but also included new staff to assist in administration, monitoring and evaluation (research staff, administrative support staff, the trial advisory committee and me as researcher/evaluator). Research staff included those specifically employed to work on the study (trial staff), those who had designed the study and were responsible for overall management (core investigators) and other staff members involved in the SLSR. Details of staff roles and experience are outlined below.

### *8.3.1. Trial staff*

As discussed in Chapter 7, a designated trial coordinator was employed on the study appointed at a junior level (TC), and a designated trial research assistant (RA). These research administrators had been involved in the modelling and exploratory trial phases of intervention development since November 2002 and January 2003 respectively (see Chapter 7 for a description of their skills and experience). During the RCT, the TC was

responsible for overseeing trial administration and intervention delivery; the RA was responsible for data collection, administration and research tasks including giving presentations on the study at academic meetings. Part of the RA's role involved organising data collection for the trial that would not otherwise have been collected by the SLSR including taking blood samples from patients to measure one year outcomes. For this she received training in phlebotomy during year one.

The core investigators involved in intervention development remained as core investigators during the trial (see Chapter 7). The PI had responsibility for overall management of the trial but was also involved in some technical aspects of the SLSR, including checking data collection forms for quality prior to being entered onto the computer. The PI and I2 were also involved in delivering intervention components (academic detailing visits at the local practices) until this responsibility was handed over to the junior doctors later in the study.

### *8.3.2 SLSR staff*

Although not specifically employed to work on the trial, since the trial used data from the SLSR, all SLSR researchers/fieldworkers also contributed to intervention delivery and trial data collection. In July 2003 three researchers were employed to collect data on newly identified strokes for the SLSR (SPR4 a specialist registrar with an interest in stroke, SPR5 a junior doctor training to be a GP and NC1 a non-clinical research associate with an MSc in Health Promotion). One research administrator (FUP1) was employed to coordinate a team of nine student field workers (all training as medical students) to collect SLSR follow-up data used in the intervention and to assess outcomes. The SLSR staff were assisted by a non-clinical research associate with a background in health promotion who was involved in some aspects of data collection

(NC2). At the start of the trial a research administrator was also employed on the SLSR to conduct administrative tasks some of which had a direct influence on the trial including identifying new stroke patients and entering data (Admin1).

### *8.3.3. Statistical support*

The trial had a nominated senior statistician (SS1) responsible for advising on statistical aspects including providing power estimates for the main outcomes, advising on randomisation and analysis. The statistician was based off-site and was on maternity leave at the start of the trial, which meant that most statistical support was provided by junior statisticians (JS2, US and JS3). US had expertise in statistical methods for cluster RCTs but was not employed to work either on Stop Stroke or the SLSR.

### *8.3.4. My role as researcher evaluator*

Although I had considered myself a core investigator during the development phase of the intervention, initially I did not consider myself to be a core investigator during the RCT. Since I was to be evaluating the study, we (the core investigators and I) felt that it would be better if I were not involved in management, technical or administrative processes (I would be unable to evaluate my own work). I went overseas from October to June during the first year of the trial but despite my physical absence, I still provided technical and advisory support throughout the trial.

### *8.3.5. Advisory group*

As with intervention development, the trial was overseen by a steering group who met yearly in August (see Chapter 7 for a list of advisory group members for the main trial). Trial staff and statisticians but not the SLSR team attended advisory group meetings.



Attendance was generally good although GP1 only attended the first meeting of the group and SS2 declined to attend any of the meetings. SS1 also did not attend any meetings (due to an administrative error she was not invited to the first meeting and did not subsequently attend the second or third meetings).

Each year at the meeting I gave a brief presentation on the study covering the MRC requirements for conducting RCTs (including eligibility, recruitment, follow-up, missing data and a chance to raise any problems). The group then discussed trial progress and made recommendations for the way forward. The minutes were taken by one of the research administrators and distributed to the group.

#### **8.4. Conduct of the Stop Stroke Trial**

Prior to the start of the trial, efforts were made by the study team to ensure that recommendations for good practice were followed.<sup>336</sup> In addition to appointing the TC and an advisory group, the core investigators produced a detailed study protocol, conducted staff training and considered issues of ethics and consent. Each of these processes is outlined below.

##### *8.4.1. Study protocol*

The study's detailed protocol was developed to gain funding for the study in 2002. The protocol outlined details of how the intervention components worked, trial process including randomisation methods, details of outcome measures and estimation of statistical power. The intervention itself comprised two main components: academic detailing visits to GP practices; and production and delivery of individualised secondary prevention plans to patients, carers and professionals (see Chapter 7).

The protocol specified that the intervention would be tested in a cluster RCT in which participants would be allocated to one of two groups, the intervention arm or control arm. General practices in the SLSR area were randomised to one arm or the other and then all subsequent SLSR patients at a given practice would receive either the intervention or 'usual care'. This method of cluster randomisation was utilised to prevent 'contamination' of the control group, in other words to ensure that participants in the control arm would not be able to access the intervention. Randomisation was stratified by practice type (whether single or multiple-handed) and practice size. It is debatable whether such factors have a significant impact on patient care.<sup>338,339</sup> However, stratification aimed to ensure that different types of practice and those with very large list sizes were roughly evenly distributed between the two arms.

Key outcome measures included prevalence of uncontrolled risk factors (use of antihypertensives, aspirin and smoking cessation). The study also aimed to influence a number of secondary risk factor control outcomes including control of cholesterol, diabetes, atrial fibrillation, obesity and heavy drinking.

A power calculation was estimated to identify how many participants were required to give the study enough statistical power to investigate the impact of the intervention on the key outcomes. The calculation was based on existing SLSR recruitment figures and suggested that if at least two-thirds of SLSR patients took part in the study over a three-year recruitment period, enough patients (315 in total) would be recruited, giving moderate power (80%) to detect a 21% increase in antihypertensive use, a 29% increase in smoking cessation and a 17% increase in aspirin use. The estimation assumed that the SLSR recruits 225 patients per year and that outcome data would be collected on at least 70% of those agreeing to take part.

The protocol also outlined recommendations for ‘blinding’ trial staff and participants. ‘Blinding’ refers to the process for preventing those involved in the trial from knowing which arms of the trial participants have been allocated. Blinding can occur at a number of different levels: recipients of the intervention may be blind as to whether they have received the intervention or the control; health care providers may be blind as to whether the recipient has received the intervention or not; those administering the intervention may be blind as to whether they are administering the intervention or a control (alternative intervention or placebo); those collecting data or those conducting analysis can also be blind as to which of the two groups is intervention or control.<sup>65,340</sup>

Blinding aims to limit bias in the way trial participants are treated. In the Stop Stroke protocol all trial and SLSR staff responsible for collecting data were ‘blind’. This meant that at the start of the trial, these staff did not know to which arm of the trial patients, GPs and practices had been allocated. GPs and patients themselves could not be ‘blind’ because the investigators thought that it would be obvious to them during the trial whether they were receiving the intervention or not. Similar problems of ‘blinding’ have been reported in relation to other types of complex intervention including in RCTs of alternative therapies such as hypnotherapy and Ayurvedic medicine.<sup>341,342</sup>

In addition to the protocol a separate manual was produced (by me) outlining step-by-step instructions on how to produce secondary prevention plans. The manual included a list of ‘trouble-shooting’ tips on how to deal with anticipated problems in producing plans (such as what to do if particular error messages appeared when executing the computer files, or what to do if new drugs were developed and new coding needed to be added). The manual also listed a number of quality control checks to be conducted by the research administrators before plans were distributed to patients. These aimed to ensure data and advice provided were accurate and ‘safe’. They included checking the



advice provided on medication and contraindications for medication, checking for spelling mistakes and stylistic problems.

#### *8.4.2. Ethics and consent*

Ethics approval was obtained from two local hospital research ethics committees. Prior to the start of the trial all GPs at practices within the recruitment area were sent a letter outlining the study and providing a description of the intervention. GPs were informed that participation was voluntary but if they chose not to participate, they needed to ‘opt out’ of the study by contacting the study team rather than ‘opt in’. GPs were informed that individual patients would be asked for consent to participate prior to inclusion in the study. At this stage, no GPs opted out.

The procedures for gaining consent from patients were informed by existing SLSR process. It was the research administrators’ responsibility to ensure informed consent was properly sought and that consent forms were signed. All consent forms were stored in a folder in the trial office. The computerised mechanism for producing the intervention ensured that patients and professionals were unable to receive a secondary prevention intervention plan without the researcher specifically indicating on the SLSR forms that the patient had consented to participate.

#### *8.4.3. Expertise and training*

All core investigators and trial staff had worked on the study for at least six months prior to the start of the trial and all had been involved in the development of the intervention at various stages (Chapter 7). All staff were given copies of the protocol and the trial manual and were familiar with the SLSR. All staff had been involved in discussions of eligibility criteria prior to the start of recruitment and one of the research

administrators and I had been involved in the randomisation process with the PI, SS2 and US. The research administrators were given specific training sessions (by me) on using the computer system to produce the secondary prevention plans and on how to monitor trial recruitment.

Lines of responsibility were established for addressing unanticipated problems with trial process not outlined in the protocol, should they emerge during the trial; if the research administrators had queries regarding eligibility or problems with trial process they would present them to the PI. If they had problems with technical issues related to the computerised component of the intervention they would email their queries to me.

The advisory group decided prior to the start of the trial that it would not be necessary to have an additional data-monitoring group to check for adverse events since there were no anticipated adverse 'side effects'. Instead, recruitment was monitored at fortnightly meetings of the trial staff and the PI. Recruitment figures were also presented at a quarterly local independent research group meeting by the research administrators and to the trial advisory group on a yearly basis by me.

## **8.5. Trial process**

The main processes took place on a weekly rather than a daily cycle. In any given week the following procedures were initiated, although exactly which procedures took place differed during the course of the trial (for example outcome data collection did not start until year two).

### *8.5.1. Identifying eligible patients*

The first stage of the trial process involved identifying patients eligible for inclusion into the trial. The process was integrated into the SLSR routines for identifying incident

strokes. Twice a week a research administrator would phone specific hospital wards and community contacts ('notification sources') to identify potential stroke patients. Once a week, an administrator would also go in person to key wards at the hospital to identify potential stroke patients.<sup>17</sup> The information gained about potential recruits was transferred into a 'notification book' and onto a computer database for use by all SLSR staff. Those responsible for trial and SLSR recruitment then checked each patient against those already recruited and visited any new patients (or at least looked through the patient's hospital notes) to decide whether they had had a stroke and if so, whether they were eligible for any of the SLSR research studies (including the trial).

#### *8.5.2. Obtaining consent*

The second stage of the trial process involved gaining informed consent from participating patients. If the patient was eligible for the trial, the researcher responsible for completing the initial SLSR questionnaire explained about the intervention and the trial and asked the patient for consent to take part. For patients unable to give informed consent themselves their next of kin was asked for 'assent', that is consent on the patient's behalf. In some cases, the researchers were unable to see the patient (or next of kin) in person, in which case he or she phoned to explain the study and then sent a copy of the consent form, together with a pre-paid envelope so they could sign and return the form if they wished to take part.

#### *8.5.3. Collecting patient data*

Once informed consent was given, the researchers started to collect data using the SLSR questionnaires. The questionnaires were divided into four parts specifically for trial purposes. Only parts one to three included questions to collect data relevant to the trial.



Part one was used to collect data that were relatively easy to access but the form could not be completed until after two weeks post stroke since it included information on the patient's state at two weeks (although this data was not relevant to the trial). Part two collected data which the staff found more difficult to collect such as body mass index and diagnoses of risk factors since the stroke, which required waiting for test results that might take longer than two weeks to process (including diagnosis of diabetes, atrial fibrillation, high cholesterol). Part three collected data relating to discharge information such as medications prescribed on discharge that could only be collected once the patient's discharge summary had been completed.

Meanwhile the SLSR follow-up team conducted interviews with patients (or carers) to collect follow-up data, some of which was used in the three and six month follow-up plans. These interviews were conducted in the patient's place of residence (own home, nursing home or in hospital if patient had not yet been discharged). Student field workers assisted with data collection at the follow-up time points and each student was allocated responsibility for a batch of interviews one month before the follow-up was due (i.e. a three month follow-up interview was allocated to the field worker two months post stroke). When a batch of interviews had been completed, the field workers returned the forms to the office for data entry. The field workers were instructed to conduct the interview on or as close to the follow-up date as possible. If the field worker had difficulty identifying the patient or conducting the interview the SLSR follow-up team took over the responsibility for chasing up the patient. This 'chasing up' process involved phoning on a number of occasions to arrange a visit; sending a letter to the patient to arrange an interview date; and as a last resort, conducting a 'cold call' at the patient's address if no response was obtained. If the research administrators had

problems identifying the address at the follow-up date then they contacted the patient's GP to try to track the patient down.

#### *8.5.4. Data processing*

Completed data collection forms were returned to the office and checked for errors (cleaned) by the PI. Forms were then passed to the research administrators who entered the data onto the SLSR computer database. Each form was entered twice into separate files and then the files validated against each other to check for errors (a process known as double entry).<sup>337,343</sup> The administrators checked through the forms to identify patients eligible for the trial and entered their details onto a trial specific database. The team used the database to keep track of who had been recruited and to highlight when various intervention components were due for delivery. It was the research administrators' responsibility to coordinate between different trial and SLSR staff and to remind those collecting data of the deadlines for returning forms. The timing of data processing was crucial to intervention quality. If the forms were not returned within the specified deadlines of 6 weeks, 4 months and 7 months post stroke (later extended to 10 weeks, 5 months and 8 months post stroke) then the patient and GP intervention plans could not be produced. If only parts of the form were returned then the plan would contain little advice or information for the patients, carers and primary care team.

#### *8.5.5. Producing intervention plans*

Plans were not always produced on a weekly basis (since this was subject to trial recruitment) but if a plan was due, one of the research administrators initiated the plan production process, exporting the data from the SLSR database so that it could be used in the trial programmes (see Chapter 7 for a detailed description of the process). If the

computer programmes identified errors then the administrator had to go back to the original forms to check the source of the error (for example if the wrong date of birth had been typed onto the SLSR database this would result in an error and the process of producing plans would be halted). If the administrator could not resolve the problem he or she would check with the other administrators, one of the team's statisticians or me to identify a solution. In some cases this process took a number of days. Once all the safety checks had been passed, the intervention plans were produced and printed out in hard copy form. The administrator then hand checked the plans against the checklist provided in the manual. If further errors were found these needed to be resolved and new plans produced. The administrator made a hard copy of each plan as a record of what had been produced. The originals were then sent out by post or delivered to the patient in hospital by the administrator, who then finally updated the computer database to record that a plan had been sent.

#### *8.5.6. Organising and conducting GP Practice visits*

In addition to producing the secondary prevention plans the intervention also involved academic detailing visits from stroke specialists (the PI and I2) at practices allocated to the intervention arm. The administrators were responsible for identifying and liaising with practice staff and organising each visit, which was conducted either as part of an existing practice meeting or as a stand-alone visit from the specialists. The specialists provided information on the SLSR, the trial, the recently published RCP guidelines on best practice in stroke care, as well as details of local stroke services (the newly developed TIA clinic) and components of the local Modernisation Initiative focusing on stroke service development.



#### *8.5.7. Outcome data collection*

The final piece of data collection (trial follow-up) was also integrated into the SLSR data collection process. All trial patients also needed to have blood tests conducted. The RA and research administrators were responsible for finding out which patients needed specific tests, organising the tests and analysis of the results. Tests included HbA1c for those previously diagnosed with diabetes; cholesterol level for all patients and cotinine level for those patients who had reported smoking at any time point either at the time of stroke or since. As with the other follow-ups, these interviews were conducted in the patients' own home. The information was collected using the standard SLSR questionnaire and entered by the researcher responsible for data collection.

### **8.6. Problems with trial process and intervention implementation**

According to published recommendations, the study fulfilled criteria for 'ideal' trial conduct. However, despite being an ideal study in theory, in practice, a number of problems related to trial conduct and intervention delivery emerged during the course of study. These may have impacted on intervention efficacy. They related to four broad themes (i) those related to the study protocol including unrealistic expectations of trial process; (ii) those related to staff understanding, communication and motivation leading to protocol deviations (iii) limitations of the pilot work (modelling and exploratory trial phases) and (iv) wider problems related to the trial environment.

#### *8.6.1. Inadequacies of the Protocol*

Although a detailed protocol was produced at the start of the trial, problems emerged during the course of the trial as a result of the complexity of the intervention, which had

not been anticipated prior to the start of the trial and were not covered in the protocol. These are outlined below.

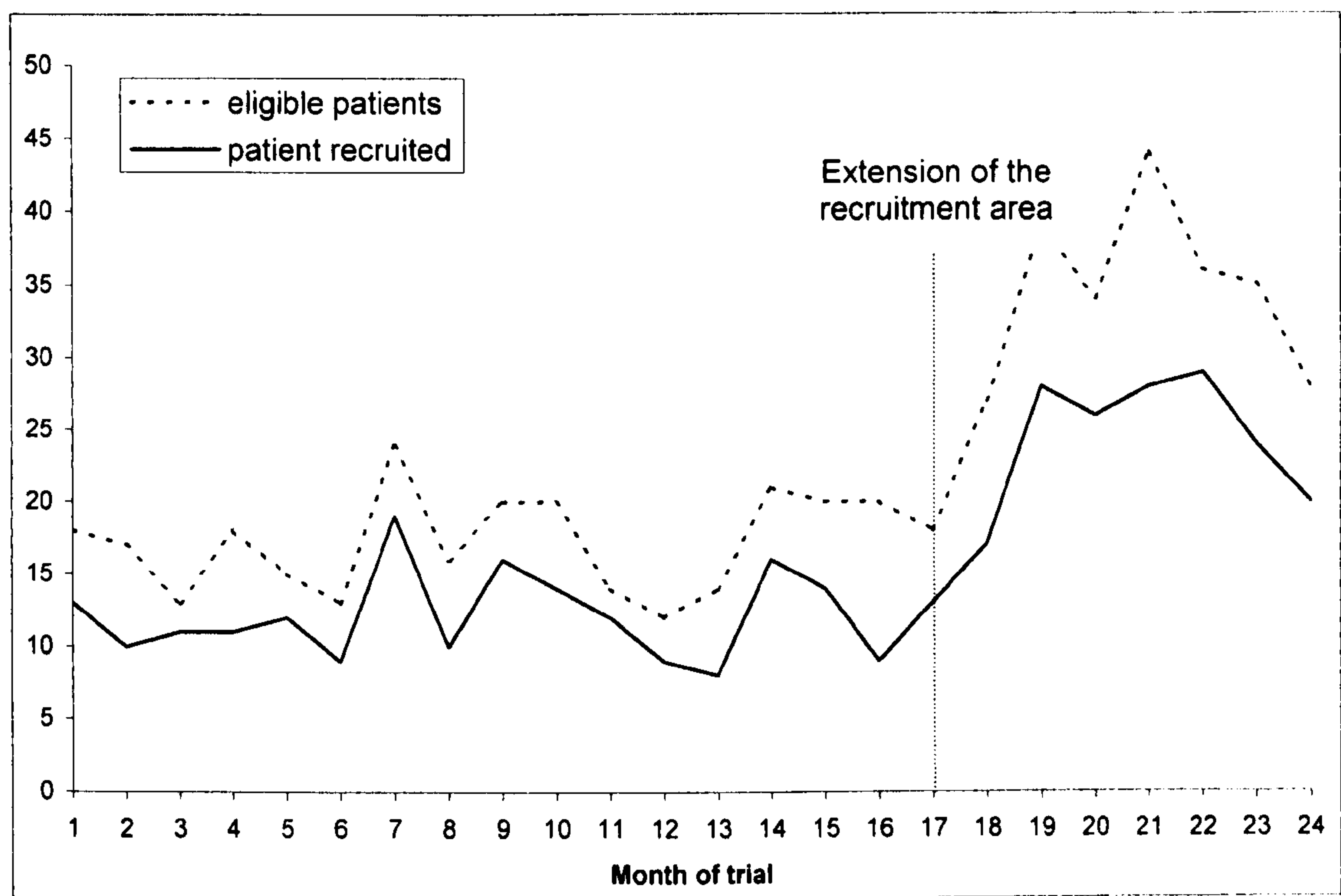
#### *8.6.1.1. Inadequate recruitment estimates*

Although a detailed power calculation was presented in the protocol, by the end of year one it became clear that the recruitment estimates had been over optimistic. By August 2004 figures suggested that the trial was under recruiting (9.4 patients per month instead of the 12.5 patients per month anticipated). The power calculation and recruitment estimates had been determined using 'real' data. However, they had been based on yearly incidence figures for the number of patients surviving to three-months post stroke and not on the number of stroke survivors identified within a relatively short time period since the stroke (for the purposes of the trial, within six weeks of the stroke). SLSR staff informed me that both very mild and very severe strokes were often notified late to the SLSR and this had not been taken into account. For patients who died very quickly from their strokes this would have little relevance to trial process since even if they were identified quickly the patients would still not have met our eligibility criteria. By contrast the mild strokes would have been eligible had they been identified more quickly and potentially would have been those most likely to benefit from the intervention.

The problem of under-recruitment was discussed at the second steering group meeting and as a result the PI proposed extending the study area to increase recruitment. The area was extended in November 2004, with an extra 10 practices recruited and randomised. By July 2005, the extension was starting to have an impact on recruitment meaning that recruitment estimates were now over the 150 patients per year estimated in

the protocol. Figure 4 shows the numbers of patients eligible for inclusion in the trial and those actually recruited over the first two years of the study.

**Figure 4. Monthly recruitment rates during first two years of trial.**



Within the first two years of the trial 466 stroke patients who were potentially eligible for the trial were identified by the SLSR team. Of these, 12 were not registered with a GP practice and nine were registered with a practice not included in the original randomisation lists. Two practices were subsequently recruited to the study and randomised; the remaining seven were not. Thus in total 444 patients were eligible for inclusion in the trial, of whom, 382 gave consent to participate and were randomised into the study.

The proportion of potentially eligible stroke patients identified by the SLSR and the proportion of patients recruited to the study did not increase at the same rate. The mean difference between rate of eligible patients and recruitment rates significantly increased



after the extension in November 2004 (9.5 patients per month) compared to before the extension (5.1), raising questions about the types of patients recruited and the generalisability of the findings to the stroke population as a whole (two sample t-test with pooled variance,  $t=3.82$ ;  $p<0.0001$ ).

At the steering group meeting in 2005 yearly follow-up rates were presented for the first time. There had not been enough data to explore follow-up until this point and follow-up had not been investigated in the pilot evaluation. The estimates showed a drop out rate of 40%, 10% higher than anticipated in the power calculation. As with trial recruitment, one possible explanation is that the original estimates were made based on SLSR data not necessarily collected at the appropriate time point for the trial (in practice, one year follow-up data could be collected at any time after one year post stroke). Alternatively, since recruitment estimates in the protocol had been based on patients surviving until three-months post stroke and in practice the trial was recruiting anyone surviving to six-weeks post stroke it is possible that those recruited had a higher death rate than anticipated in the original estimate.

#### *8.6.1.2. Lack of consensus about patient eligibility*

At the start of the study it was agreed that all patients on the SLSR registered with a participating practice would be eligible for inclusion in the trial. However, explicit eligibility criteria were not outlined in the protocol. Confusion over eligibility began even within the first two weeks of the start of the trial. The research administrators were unsure about the designated start date and whether starting on 21<sup>st</sup> July 2003 meant that all patients would be recruited who had had their strokes since 21<sup>st</sup> July, or whether all SLSR patients currently on the stroke wards would be included. To clarify things, I recommended that we should take all patients whose *stroke* had occurred after 21<sup>st</sup> July.

However, a week into the trial no patients had been recruited and the PI recommended that all newly recruited SLSR patients should be included regardless of stroke date.

The decision raised further questions about eligibility that had not previously been considered. It also raised questions about what exactly the intervention components were. The theoretical phase findings had suggested we needed to deliver the intervention at multiple time points relevant to the patient and so the original aim had been to send patients three consecutive secondary prevention plans (see Chapter 7, section 7.3.4). In order to do this, patients needed to be identified as soon as possible after the stroke. To include all newly identified patients regardless of stroke date meant including those for whom it was already 'too late' to deliver the first part of the intervention. Thus some patients could potentially receive all three 'doses' of the intervention whilst others would receive only one or two.

Since the original power calculation and funding had been based on all surviving SLSR patients being eligible, I (as a member of the trial team) proposed that we would include all patients notified to us within 6 months of their stroke (that is, they were eligible to receive at least one 'dose' of the intervention). Otherwise it would have been impossible to hit the required recruitment estimate of 150 patients per year. This decision was approved by the PI and I1. At the same time, I also clarified the eligibility criteria for receiving each specific dose of the intervention; patients eligible for the initial plan must have been recruited to the trial within six weeks of stroke. Patients eligible for subsequent doses must have been recruited to the trial by three months and six months respectively. Plans must then be sent to patients and professionals by eight weeks, four months and seven months respectively. These decisions satisfied the ethical requirement that we should be able to recruit sufficient numbers to detect statistically significant differences. However, in doing so we had been forced to change the intervention itself.

Of those recruited in the first two years of the trial, only 27.7% (54) were sent all three intervention plans; 30.3% (59) were sent two plans; 26.2% (51) were sent only one plan; and 15.9% (31) were not sent any intervention plans at all. In other words satisfying RCT requirements (the need to recruit sufficient numbers within a given time frame) had forced us to compromise the theoretical grounding of the intervention.

Questions over eligibility continued to arise during the course of the trial in relation to other problems such as what to do if a patient moved GP during the trial or what to do if the patient did not have a GP at the start of the trial but subsequently registered with a GP during the course of the trial. Pocock argues that trial protocols need to provide comprehensive details of trial operations including requirements for patient entry, treatment and evaluation.<sup>65</sup> However, some of the research administrators reported that when they tried to raise questions in advance about what they should do in different potential scenarios they were told that this was a 'pragmatic trial' and therefore problems would be addressed as they arose. In some instances it was felt that decisions could have been made earlier, such as decisions on what would happen in the patient moved GP practice during the trial:

I know everyone kind of says it's a pragmatic trial but there are some things, probably, I think we could have easily sort of sat down and sorted out at the beginning, like for example, if somebody has a certain GP when they have their stroke and they swap GPs because they're may be out of area [sic], or that someone is in the control arm and they swap to a GP and is in the intervention, that type of thing. (Research administrator, 2004).

SLSR analyses revealed that in practice only a small minority of patients changed GP during the first two years (6, 1.5%). Thus lack of clarity over practice changes may prove to have little impact on trial outcomes. However, this seemingly insignificant problem may have had broader implications in terms of staff understanding and morale. At each yearly interview the research administrators discussed confusion and frustration



resulting from lack of detail in the protocol (and particularly in relation to what they should do if a patient changed GP during the trial). Lack of detail affected confidence, particularly at the beginning of the study:

I think in the beginning I used to feel like a nan [sic] because I always used to have to go in to ask questions, because I didn't know. There was nothing written for me. (Research administrator, 2005).

The same administrator went on to explain that even though she now felt that she understood the appropriate procedure for dealing with patients who changed GP, she still found it frustrating that such issues had not been clarified at the start of the trial:

Well I know what the procedure is now. But what I'm saying is, that wasn't a hard thing to develop from the start and stick with, if you get what I'm saying. It could have been said from before and written down. (Research administrator, 2005).

Clarifying the specifics of trial process may be particularly difficult in the case of a complex intervention trial where potential deviations from the norm are numerous and solutions cannot always be identified prior to the start of the trial. However, the impact of detail about seemingly insignificant numbers of patients (in this case what to do about patients with new GP practices or those whose GP moves during the trial) may be important in influencing trial operations.

#### *8.6.1.3. Limitations of quality control measures*

Although quality control procedures had been put in place at the start of the trial, it became clear during the course of the trial that they were insufficient. In March 2004, one of the research administrators wrote in her process evaluation diary that a patient she had visited had shown her a copy of an intervention plan that had suggested that he was not taking his blood pressure tablets appropriately when he felt that he had been. She checked what had been sent to the patient and it emerged that there was a

programming error that meant that patients taking antihypertensives were being provided with inappropriate advice. The issue had only emerged because the patient himself had alerted the team to the problem. She wrote in her diary:

As I enter the six-month forms and [another administrator] just produces them there is no real checking process...I have discussed this procedure in the light of the current problem and [one of the administrators] will now go through the questionnaire and management plan together to ensure no incorrect information is sent out.

(Research administrator, 12/03/04)

The PI had been under the impression that the research administrators checked the advice in each plan in detail against the original SLSR forms to make sure all data were accurate. However, none of the administrators were clinically trained and it would have been difficult for any of them to ascertain from original SLSR forms what 'accurate' secondary prevention advice should be. Prior to the start of the trial as an intervention developer, I was under the impression that they would check the items listed in the checklist provided in the manual (checking that medications were not contraindicated, that spellings and style were correct). The administrators thought that the programmes had been sufficiently tested and no checking at all was required. However, with the problem highlighted through the process evaluation, the team were able to intervene to improve quality control; I was able to modify inaccurate computer programming and the PI asked for all future plans to be checked against original forms.

#### *8.6.2. Staff understanding, training and support*

In addition to being given copies of the protocol, all staff had been given training in trial process prior to the start of the trial. However, when I interviewed trial staff a year into the trial, I found little understanding of trial process including aspects of trial recruitment and data collection outlined in the protocol.

#### 8.6.2.1. *Understanding the protocol*

Lack of understanding of the trial protocol may have influenced who was being recruited (or not recruited) into the trial. One of the researchers responsible for recruiting patients described how she had been confused about the inclusion criteria and had been recruiting patients who she was later told were not eligible:

in terms of the inclusion and the exclusion of people in the trial, I know we – at the beginning it was kind of decided that we weren't going to exclude anybody, everybody was going to be included but obviously if they died, if they passed away before their six week point...However, when I was kind of in the process of this, [the PI] checks through all the forms and I'd just written on one the forms that, I think I'd written at the top, I think 'poor prognosis' or something like that, along the lines of that, that this person was very poorly. And then he came to me and said, 'Why have we included this person in the trial then?' And then I sort of said, 'That's what I thought we were meant to be doing.' But then [the PI] said, 'But that's actually something, when someone's got a really, really poor prognosis, then we're not going to be including them in the trial.'

(Researcher responsible for recruitment, 2004).

Members of the research team were aware that there were some areas of the trial that they did not properly understand. In particular they found the lack of defined solutions for potential problems difficult to deal with on a day-to-day basis and blamed protocol deficiencies.

Research administrator: We deal with it as and when it comes up. It's on the ball problems solving kind of, you know. But, it's not a consistent thing, I don't think, because I just think that every time something comes up, you could have a similar situation that came up six months ago and the same decision would not be made. That's what I think because I just know that people forget what they've said and things just get awry which is why I think – I think even for a pragmatic trial, there should be some ground rules where you could be flexible on some things but not everything. You must have some sort of – this is our ...



JR: A protocol.

Research administrator: Yes and not just a protocol to give the Steering Committee ... but a protocol that when we're on the ground working, we can use it to assist us and problem solving our everyday problems that we don't have to come and ask you every time, 'Oh this happened, what do I do?' We just know, we have it written there, refer to it.

(Research administrator, 2004).

Such details were not presented in the trial protocol but some of the concerns expressed were issues that had been discussed prior to the start of the trial (such as what to do if a patient changed GP during the trial). The problem here was that different team members did not agree on the solutions to different problems. The administrators felt that the root of the problem was that they did not have a written record of such decisions. However, neither did they feel that it was their responsibility to make note of what had been discussed at meetings.

People tend to forget what they've said, or the agreements they've made...I don't really have the presence of mind to be writing down everything that you've just said. We have to make certain assumptions. If I tell you you told me something, [then] you told me something to do. So don't come back and say, 'Oh why are we doing this?' Now, 'write it down, let us agree, so whatever happens we can say that on this day, we had this meeting and we agreed to ten points as to what we would do.' (Research administrator, 2004).

Although the trial team were aware of some of the problems they were experiencing, other implementation problems were not recognised and only emerged as a result of the process evaluation itself. For example, misunderstandings emerged in relation to the recruitment figures. Recruitment figures had been reported to the PI roughly on a fortnightly basis throughout the first year but those doing the reporting did not fully understand the figures they were presenting. The administrators had been unaware that they were under recruiting and had informed the PI that recruitment was on track. They

had been under the impression that the trial need only recruit 315 patients in total (100 patients per year) rather than the 450 outlined in the proposal.

#### *8.6.2.2. Training and support*

The research administrators also seemed uncomfortable with the backup systems in place for dealing with queries on an ongoing basis (going to the PI or emailing me). They felt they needed training and support to understand trial problems rather than instructions on what to do to resolve a particular problem.

We kind of felt just a bit, sometimes just a bit like, 'okay we don't really know what to do,' and to go to the PI, you do need to go with a solution, you can't go with, 'Argh, I've got all these problems and we just don't know what to do about them.' And I do think it is good to think through yourself about what the kind of solutions are. But sometimes when you just get to the point where you've kind of been thinking about it, thinking about it...but you just don't have any idea really of what you're doing. And you just feel really lost going, 'Oh my God, this is all going really wrong.' And you kind of go to someone and they say, 'Oh ring this person,' and you ring this person and they're of no help whatsoever. And you go back and they say, 'Well didn't you ring the person?' And you say, 'Well yes but they were of no help.' (Research administrator, 2004).

Pocock (2004) recommends that regular meetings are held with all trial participants for communication and feedback on trial progress and to 'air any problems'.<sup>65</sup> During year one, meetings had been held roughly fortnightly with the PI, the RA and the TC but I1, I2, the other research administrators and SLSR data collection staff had not been present and I had been abroad. When the problems with trial recruitment emerged, I1 and I set up new fortnightly meetings together with the PI, the research administrators and JS2 focusing on trial recruitment and management problems. At first, these meetings proved useful in that they ensured routine monitoring and also shared responsibility for trial problems:

it doesn't feel quite so formal. I think sometimes when we go to [the PI], it's very much like...you have to go with a kind of the solution bit. I sometimes just like with this whole blood taking thing, I was just like, 'Argh, I just don't know what to do.' And sometimes it's quite good just to maybe brainstorm things or get an idea of what other people think, rather than have to have a solution to everything. And so, yes, I think they are very useful, really useful. (Research administrator, 2004).

However, the continued identification of problems and feedback from the process evaluation may also have had a detrimental impact on staff morale. A year later the administrators saw the meetings as just another routine that did not help in resolving the trial problems.

Sometimes it always feels a bit of like a blaming, 'Why hasn't this been done, what's going on here?' (Research administrator, 2005).

This started to be reflected in attendance at the meetings which went from all trial team and core investigators (except I2) attending regularly in 2004, to at least one member being absent from every meeting by 2005, as illustrated in my own diary entry in July 2005.

I am feeling quite down about the trial again today....at the last Stop Stroke meeting [the PI] did not attend. He said that it was not in his diary. I am not sure how to take this since every Tuesday that there is a SLSR meeting there is also a Stop Stroke meeting...I also missed the last meeting and came into my office to say happily that he had [another] meeting and so wouldn't be able to attend. It is part joking but I feel there is a real element of dread about these meeting[s] now...they symbolise something negative. (JR diary 23/06/05).

The meetings were also limited in that some of the problems affecting the trial were broader resource, staffing and management issues related to the SLSR (which influenced trial recruitment, follow-up and intervention delivery).

I think probably one of the main things that's been difficult is the fact that often a lot of the register, things that were maybe not working quite so well in the register, lap over to Stop



Strokes, they sort of get mentioned in the register and we try to mention them in the register meeting and we try to sort them out there. ... For example, the fact that, ...I need some more help with initialling, is it something then to come in to Stop Stroke meeting ... I don't know. It can't really be resolved. (Research administrator, 2005).

Since the SLSR team were not present at the Stop Stroke meeting and those present did not have the power to instigate change it was impossible to address broader SLSR concerns within this forum.

### *8.6.3. Limitations of the pilot evaluation (exploratory trial)*

Although a pilot evaluation had been conducted prior to the start of the trial (see Chapter 7) some of the problems emerging during the course of the trial may have resulted from limitations of that evaluation, in particular those discussed previously in relation to trial recruitment, follow-up and intervention delivery.

#### *8.6.3.1. Lack of testing of recruitment and data collection processes*

Data collection systems for the SLSR had been in place for eight years prior to the start of the trial. However, some aspects of the data collection process were changed to fit with trial requirements and these changes had not been tested in the pilot. One of the research administrators felt that some of these changes, in particular the identification and registration of stroke patients within the time frame required for intervention delivery, did not work.

... we were running on such a kind of 'full steam ahead' that if one little thing goes wrong, then it's just like, right and then it's just going to be a bit of backlog and a bit of backlog. But I think again that's the way the register has always been run. There's always been a backlog built up...and I suppose that just doesn't fit with Stop Stroke...I suppose with Stop Stroke, it's just like, we really can't have a backlog because we need everyone we can have

within the sort of 6 weeks. I suppose that's one of the things how Stop Stroke and the register have maybe clashed a bit. (Research administrator, 2005).

In the pilot study the data collection processes had been conducted and processed with additional assistance from a public health trainee and were only collected on a small group of 25 patients (see Chapter 7). Processing had involved only small amounts of data relevant to the trial rather than all data collected by the SLSR, thus problems with backlog had not emerged. One of the research administrators explained how the broad inclusion criteria for the main trial made it particularly difficult to gain patient consent within the first six weeks of stroke since some patients were difficult to see in person or had other health or psychological problems and could not sign consent forms themselves.

Getting consent in the time period needed has definitely been something that's been tricky, because if the person – it's alright if they're in hospital and they're kind of with it, so you can get consent. But I think the problem mainly comes when they get discharged and you speak to them on the phone and you explain everything, you ask all the questions you need to process the initial form and you send off the consent forms in the post and you don't get them back, that can be tricky. (Research administrator, 2005).

Similar difficulties emerged in gaining carer consent. Involving carers in secondary prevention management through sending plans to nominated main carers was an important component of the intervention (Chapter 7). Two years into the trial only 7/382 patients had given consent to contact a nominated carer. Difficulty gaining consent caused delays for trial recruitment.

Despite attempts to reduce delays as a result of the pilot work (which had led to splitting the initial SLSR form), delays also existed in the data collection process. Getting the patient's height (or demi-span) and weight and their behavioural risk factors prior to stroke (alcohol use and smoking) proved difficult since these data were not always recorded in the patient's notes. In the pilot evaluation all included patients had been

seen by the researcher in person to collect data. However, in the main trial some patients were not seen in person at the time of stroke and it was not possible to gain consent or collect risk factor data in time to produce the intervention plans.

One of the data collection team also noted that data on secondary prevention medications were particularly difficult to collect and return to the office in time to be processed for the intervention. The process of data collection was further complicated if the patient had not yet been discharged from hospital.

I think it would just be so much easier just to really keep on top of ...if all we had to do was focus on a person and [think] 'right, they've been discharged'- instantly... get the discharge summary (Researcher responsible for data collection, 2005).

Problems collecting medication data prior to discharge had been identified in the pilot evaluation but recommendations to only deliver the intervention to patients on discharge had not been taken up. At the time the PI had felt that it was important to create a neat trial environment in which all patients would receive the same components at the same time points. Thus in the main trial, the data collection staff had to make judgements about when to conduct the data collection and what data to include to meet the requirements of intervention delivery. They then had to go back after the prevention plans had been produced to collect further information (when the patient was eventually discharged from hospital) to be used for the SLSR and subsequent intervention plans. One of the researchers responsible for data collection explained her thought process in this scenario:

'have they been discharged?' 'Oh right, okay but it's, you know, five weeks [so there is still time left to collect further data].' 'Oh they haven't been discharged yet, but we're at six weeks [the time at which the data is due].' And it can get really complicated.

(Researcher responsible for data collection, 2005).



This complicated system made it difficult to collect and enter data within the given timeframe for the trial but also suggested that these problems would remain outside of the trial if it were rolled out in routine practice.

The research administrators and data collection team felt that there were fewer problems with follow-up data collection (at three and six months) than at the time of stroke. However, analysis of SLSR data revealed that only 80% of patients who had entered the trial completed a three month or six month follow-up visit and of these 10% received their three month visit more than five months post stroke (that is, not in time for the data to be used for the three month plans).

For those patients who had completed a follow-up visit, problems also emerged in ensuring data were complete. One particular problem related to the collection of blood samples at one year. The one-year follow-up interviews had started late and in her interview in 2004 one of the researchers responsible for data collection stated that she felt to blame for the delays explaining that she had not started thinking about how blood samples would be stored and analysed until one month before the tests needed to start and this was too late to arrange storage space.

I've kind of had quite a few problems with the whole blood thing. And I do think it is my fault because I should have started sorting it out a lot sooner than I did, the whole kind of process. And I didn't really realise it was going to be as complicated to sort out as what it is. And there's kind of other things that factor in that kind of in terms of getting equipment for the blood taking stuff. (Researcher responsible for one year data collection, 2004).

In a subsequent interview in 2005 she went on to explain that she also had a confidence problem about collecting blood samples from patients in their own homes despite having had additional practice with clinical supervision in the hospital. This had further delayed the start of data collection.

I think the feeling, the actual doing the training was fine, that was really smooth and quick and was perfect. I did that at [Hospital X] and they were brilliant there. And I think then it was the, sort of having the confidence of going out into the community on my own, so I needed a bit of practice within the hospital.

(Researcher responsible for one year data collection, 2005).

These delays meant that the one-year follow-up data collection started at the same time that patient recruitment expanded to the whole of Southwark and Lambeth placing considerable demands on staff time. Since SLSR recruitment and initial data collection had been prioritised, the one-year follow-up interviews were compromised.

#### *8.6.3.2. Lack of testing of intervention components*

Problems also emerged for delivering intervention components themselves, both for conducting GP practice visits and in delivering secondary prevention plans.

At the start of the trial the administrators were given the task of organising GP practice visits for practices in the intervention arm. They were instructed to start with the largest practices first since it was thought that these practices were likely to yield most patients. To begin with, the administrators were highly motivated in delivering this component of the intervention despite it requiring considerable effort. The task involved making multiple telephone calls, sending emails, letter and faxes to practice managers and GPs, as well as juggling diary commitments:

you need to call them at least once a week. Just have a block time because I mean ... I've tried every trick in the book recently. I've started calling them, I've got their emails, I email them. [then I send] just general letters. After letters, I fax them... And after all these different methods I got responses, a trickle. I reached a point of ... I said, 'Alright, I'm going to sit down with the diaries and see what dates are available.' I did this proposal meeting, with a sheet, where they could just – simple, date, time, box to tick, yes/no. And I asked for two or more dates, because even though times were free in their diary, [the PI and

12's] diaries, any time, anything could happen, so I needed to have an alternative as well because they might not be able to make it on the days or something. You know, you just need to have more than one option. And I put a prepaid envelope in it. And faxed it. So I posted and faxed it. That was probably the best thing because I think people like just having to tick it and fax it back...

...But it's a lot of hard work...it is an exercise that you have to put time into, you have to call, you have to follow-up, they're not going to follow you up, you have to follow them up. (Research administrator, 2004).

But within five months the administrators started to experience problems coordinating the diaries of two senior staff members and the busy GP practice meetings. On average only one practice per week was visited. Some practices indicated that they did not have time for a practice visit or felt that since the visiting specialists were linked to Hospital A and they did not routinely send patients to Hospital A it was not relevant to their patients. The task of visiting the practices was passed on to the junior doctors in the team, raising questions about their ability to act as unbiased data collectors. If they were also delivering the intervention they would become 'unblind' as to which practices were in the intervention arm. Despite the handover, the diary problems remained. Equally, although it was part of the protocol, those doing the visits were not committed or not able to prioritise the time needed to conduct the visits. Visits were sometimes cancelled or rescheduled at short notice:

I'll never forget, I did - this woman, basically she agreed for a date and a time and I emailed [one of the specialists] ... [the PI] couldn't make it. [Then on the day of the visit] I saw him [the specialist] there and I said, 'How was the meeting?' 'What meeting?' 'Your practice meeting today.' And he said, 'Oh I didn't, I don't have it.' Oh my God, I ran upstairs to call to apologise because these GPs are there, they have collated their diaries for this half an hour, after basically coaxing them for so long, you can't afford to miss a meeting with these practices, you're not going to give a good impression ...



So, the second time, they gave me another time and [one of the SLSR clinical researchers], I booked [one of the SLSR clinical researchers] in. And she as well – I said to [her], ‘It’s very important that you attend this meeting, because we’ve cancelled on them before and it would look really horrible if we don’t go again.’ And she was like ‘No problem I’ll go,’ but she ended up cancelling again. And the thing that pisses me off is that they don’t have to call them and tell them that they can’t make it. I have to call them and tell them. And that just grates, because it’s like, ‘Oh I’m really sorry but’ and at the time I had all good intentions. Everybody was free, it should have been done. (Research administrator, 2004).

The process of organising and conducting GP practice visits was another part of the trial which had not been pilot tested prior to the main RCT. In the end only 15/28 intervention practices in the original area received a visit and 6/10 practices in the extended area.

Problems also emerged for delivery of secondary prevention plans (which had been tested in the pilot study). As described earlier, once all the data were entered, statistical software (STATA) programmes were executed to produce the intervention plans. Despite testing some of the computer programmes for the pilot study, not all aspects of the programming had been fully tested. For example, six-month data collection was not fully integrated into the SLSR until September 2003 (after the trial had already started). Consequently there had been insufficient ‘real’ patient data to fully test the six-month computer programmes.

Programming errors emerged throughout the first two years of the study, with errors delaying production and distribution of the intervention. Errors included mismatches between the patient’s control of risk factors and the advice presented; problems dealing with data on alcohol use; wrongly numbered additional sheets; and missing test results. Although most problems were minor typographical issues, one problem that could have led to inappropriate advice being provided to the patient, was not picked up through quality control checks. In May 2004 one of the data collection staff visited a patient for

a six-month follow-up interview and the patient revealed to her that he had received the intervention. He told the researcher that he had had a gastro-intestinal bleed, a contraindication to aspirin. However, when the patient's next intervention plan was produced, it advised the patient to ask his GP whether he needed to take aspirin. The problem had resulted from a programming error in one of the computer algorithms (I had omitted gastro-intestinal bleed as a contraindication for aspirin). Although a manual had been produced and disseminated outlining the content of the programmes, the mistake had not been identified. For this patient, the plan was modified manually and the programmes changed.

One of the administrators felt that if there had been a few months more lead-time before the start of the trial then many of the problems including those related to programming errors would have been resolved.

And I don't know whether, I suppose we could have rushed in a little bit but I don't think, by sort of starting it now, I think, we could have quite easily started it maybe, I don't know, we started in July, probably by Christmas I think we really knew all the issues...but then obviously, in terms of money and stuff, with a trial like that, you can't have a pilot.

(Research administrator 2004)

Whether in practice a few extra months would have made a difference is debatable since SLSR forms and processes were continuously being modified meaning that new technical problems continued to emerge throughout the study. For example, in June 2004 the RCP published updated guidance on risk management which led to changes in the advice provided to patients; in June 2005 new versions of the initial SLSR form were produced for a European study the trial team were conducting, causing delays in data entry processes and subsequent delays for producing secondary prevention plans. As one of the other administrators argued, after two years many of the initial problems had been resolved but new problems continued to emerge. However, some form of

‘lead-in’ phase for the main trial might have provided staff with a better opportunity for consolidating trial processes, in turn improving staff understanding and motivation. In 2005 one of the administrators reflected on how trial processes had improved during the course of the study:

The trial is now on its feet, it’s now – you know, to me, in another year, or probably another two years, you will really get what you need to get, because it’s not a point where everything is on point – everything is working you know...I never thought I would be able to say it but it is! It is smooth right now. And that gives me motivation in a sense, because I can finally see – kind of like being rewarded. It’s not finished but you’re still seeing the fruit of your work, in a sense. It feels good and I think that’s also the motivation for me to try and do these entries as well, so that we can run the figures and see the difference. So I can run them, I suppose and think, ‘Right, figures are improving, that is part of my, you know, little joy.’ It’s not much but it gets me going. (Research administrator, 2005).

Delays in recruiting patients and producing the intervention resulted in a large proportion of patients eligible to receive intervention components not receiving them. One year into the trial, only 46% of patients and professionals eligible to receive the initial plan were sent plans; 67% of those eligible to receive the three month intervention component were sent plans; and 64% of those eligible for the six month intervention were sent plans. Of the three patients in the intervention arm who had given consent for a carer plan to be sent and were eligible to receive the intervention, none were sent the intervention at any time point. The administrators had forgotten to monitor plan production and delivery for these patients.

### **8.7. The trial environment**

In addition to problems of trial process, the environment within which the intervention was delivered may also have had an impact on outcomes. An ‘ideal’ experimental environment would be one in which all factors other than the one of interest (the



intervention) are held constant so as not to confound the relationship between the intervention and outcome.<sup>62</sup> In the case of clinical/pragmatic trials this is not usually possible since the interaction takes place in a real life environment where change cannot be controlled<sup>62</sup> unlike in a laboratory setting. While randomisation and control may overcome some of the problems of a changing research environment, a number of extra safeguards are usually put in place to ensure that effects can be attributed to the intervention including 'blinding' of those involved in the trial.<sup>340</sup> Although all data collection staff were initially blind as to which arm the patient had been allocated, all were 'unblind' to at least some patients or practices by the second year. I have already discussed how time commitments of the stroke specialists led to SLSR clinical researchers becoming 'un-blind' (section 8.6.3.2). However, the trial environment also led to other staff becoming aware of the trial arm for particular practices and patients. Due to resource and practical constraints the administrators were located in an office with the data collection staff. This meant that when intervention plans were produced and practiced visits organised conversations could be overheard and names of those receiving the intervention plans observed by all other SLSR data collection staff including the student field workers. On a number of occasions I witnessed an administrator discussing the arm of trial to which practices or particular patients had been allocated, with or in front of SLSR staff.

There were also a number of environmental factors, which changed throughout the course of the trial, which although not biasing the trial, may have had an impact on intervention delivery and on the effect size of the intervention. These are now discussed.

### *8.7.1. Development of local services*

The first type of environmental change involved development of local health services during the trial. A new neurovascular clinic was developed in one of the hospitals in the study area, which had not existed when the theoretical phase research had been carried out. The clinic had a particular focus on preventing stroke after a TIA but also provided follow-up for people after a stroke. Clinic staff included a doctor specialising in stroke medicine and a specialist stroke nurse. The clinic may have increased patient access to secondary prevention advice and specialist management limiting the potential impact of the intervention. The clinic also influenced trial recruitment since it affected the way patients were identified to the SLSR. Throughout the first year of the trial there had been problems with data collection at the TIA clinic (due to staffing problems and workload issues). This had resulted in a backlog of patients who were recruited late to the trial and therefore had less chance of receiving all intervention components.

Protocols for disseminating information from hospital to primary care also changed during the course of the study. At one of the hospitals in the study area a standardised discharge summary sheet was developed for recording stroke secondary prevention information. The sheet aimed to improve continuity between hospital clinicians and primary care teams. If this system worked then professionals may have had less need for the professional component of the intervention.

Thirdly, as part of the local Modernisation Initiative (a three-year programme to improve local health care including stroke services<sup>235</sup>), a stroke patient group was set up to help develop local services. Some trial participants were also members of this group and as part of the groups' activities, fed details of intervention components they had received as part of the trial to other stroke patients and service developers. One service developer subsequently decided to design his own similar intervention (an

individualised secondary prevention workbook) for stroke patients, which he aimed to implement before the trial had finished. His decision to develop such an intervention may not have been influenced by the stroke patient group but the patient feedback and the subsequent intervention were nevertheless potential contaminators of the trial. In this case, the plans for intervention development were uncovered by the process evaluation and fed back to the PI who consequently stopped the intervention from going ahead.

#### *8.7.2. Distribution of intervention components outside of the trial environment*

In addition to environmental changes outside the control of the investigators a number of environmental changes also occurred as a result of the actions of the study team, included distribution of intervention components outside of the trial environment. The patient information sheets developed as part of the intervention were distributed to a local GP in the trial (whose practice was allocated to the intervention arm). The same information sheets were also distributed to another research team (outside the study area) who aimed to place them on a national website to be accessed by anyone with an interest in stroke (patients, professionals, researchers). Distribution of the sheets to the GP could have improved their use within that particular practice. However, it could also have led to contamination if the GP then distributed the sheets to other GPs or practices in the control arm. Publication of sheets on a website could have contaminated patients or professionals in the control arm who could theoretically have access to them. In this case I intervened asking the PI to consider the impact of distribution of the intervention outside the trial context. Both I1 and I felt that according to the principles of RCTs it was not appropriate to distribute the intervention when it had not yet been evaluated but the PI and I2 argued that in this case it did not matter. They argued that distribution was



unlikely to lead to contamination of the trial since they felt that few trial patients or practitioners would access the website. They argued that it did not matter that intervention components had not been sufficiently evaluated since this was not a drug trial and patient safety was not an issue. The PI also argued that patient information was not the intervention per se but simply one of the components and thus it could not potentially contaminate the trial. In addition I2 was concerned about improving collaborative links with the other research team, which he felt took priority over adhering to trial recommendations in this case. He challenged my stance ('interference') suggesting that I was being unsupportive of sharing research expertise.

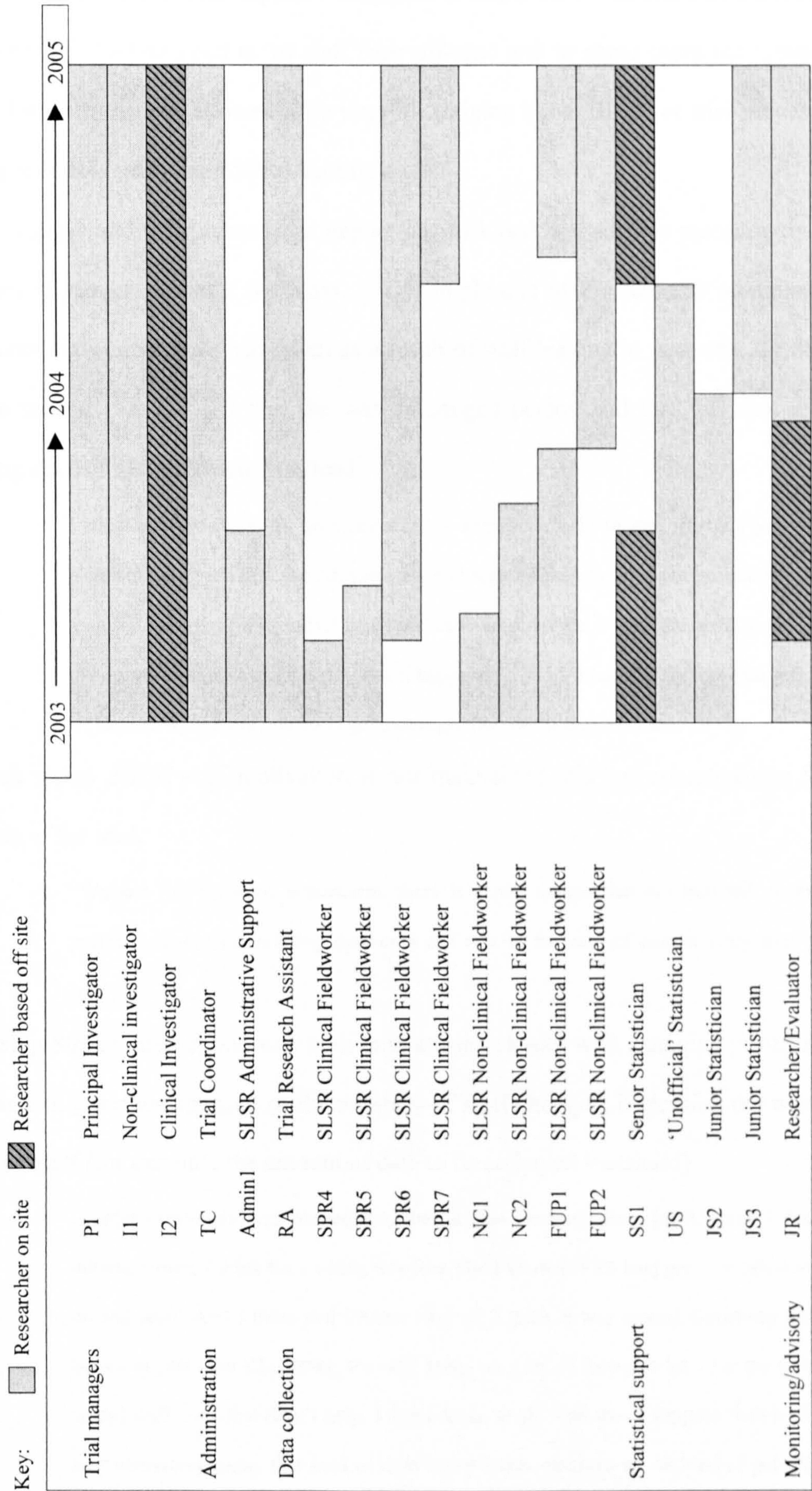
In hindsight, while it is unlikely that the environmental changes described above would have a large impact on trial outcomes, distribution of the intervention outside of the trial did nevertheless have the potential to influence outcomes. For example, distribution of intervention components to another research team had the potential to influence the effect size of the intervention, which might have been lessened if those in the control arm had started to receive secondary prevention advice not routinely received prior to the start of the trial. Equally, we know that if patients had received an intervention similar to the Stop Stroke intervention which they felt was not relevant (such as routine information leaflets) then this may have prevented uptake of subsequent individualised, more appropriate advice.<sup>270</sup>

### *8.7.3. Staff changes*

During the trial there were also a number of staff changes (Figure 5), which may have had an impact on intervention delivery and trial process. A total of 19 staff members worked on the trial during the first two years, plus nine student field workers. At the start of the trial in July 2003, 15 members of staff were involved (two of whom were



Figure 5. Staff changes in the Stop Stroke Trial in the first two years.





based off-site and provided input by telephone or email only – I2 and SS1). During the first year this had dropped to 10 staff (one off-site) and in some cases the turnaround dates for staff changes allowed little time for training about SLSR or trial process (for example SPR4 leaving and SPR6 starting).

Staff changes and their subsequent impact on workload and support mechanisms were sources of tension amongst the team. For example one of the research administrators explained how her morale had fallen as a result of staff leaving in year one. By the end of the second year she felt that she was a changed person and that this was a direct consequence of her increased workload:

I think everybody is just so stretched... – somebody said to me, '[name], you were so different when you first started, you were so happy, you were so – your personality, it's just a totally different personality.' And that really affected me. I was like, well something has to happen. It happened gradually but it happened...and I think it's because you just feel as if, you know, nothing you do is good enough. (Research administrator, 2005).

Pocock warns that if staff motivation is not maintained this has consequences for all aspects of the trial:

“Without this sense of enthusiasm, there is a real danger that the trial will deteriorate: protocol deviations, missing data or a fall rate in the rate of patient entry may occur” (p35).<sup>65</sup>

The Stop Stroke intervention was built onto a research tool with changing priorities and as research priorities changed so the numbers of staff changed, increasing the workload for trial staff (for example the amount of data to be collected increased)

....after everybody was phased out, then it was predominantly [SPR3] and I doing the initials, which, I think for a while, was fine. But I know [SPR3 has] got a lot of other things on and stuff. And I think and I know kind of, I think it was around Christmas time, just before or just after Christmas, she was going on a lot of foreign trips...for the [European study] stuff. And that didn't help, I don't think, at all. And then I suppose with [one of the administrators] going, that kind of didn't help either, because we all kind of got other bits



put on us. And I mean you can quite easily say, 'Okay I've got to prioritise this, this and this,' then it gets to the point where, if you don't – and then you've got this to do as well and if you don't start prioritising that, then it can be like two months and you haven't done it and you are meant to do it every week.

(Researcher responsible for data collection, 2004).

One of the administrators felt that her increased workload had had a detrimental impact on the quality of her work. She explained that as her workload increased, some responsibilities were compromised including aspects of the trial.

It takes away from your attention really, because you have to pay attention to so many different things. So many different bits, you have to try and kind of manage, in a sense. But something always suffers, that's the thing. Something always – when you have too much on, things suffer. It's not that you don't want to do it, I mean, it's just that you can't do everything. (Research administrator, 2004).

## **8.8. Discussion**

In this chapter I have presented findings from a process evaluation embedded within the Stop Stroke Trial. There is little guidance on the use of process evaluation in this context but in the Stop Stroke study the process evaluation was used both to highlight problems of intervention implementation and to provide ongoing feedback to trial staff to improve protocol adherence.

The Stop Stroke Trial followed both the recommendations for development outlined in the MRC Framework for complex interventions and the MRC guidelines for good practice in clinical trials. Yet problems of intervention delivery and trial conduct still emerged. The evaluation highlighted problems with trial process, which could be attributed to limitations of the protocol, problems with staff understanding, support and motivation, limitations of the pilot study and changes to the trial environment. These problems may have had an important influence on intervention delivery, which



subsequently could impact on trial outcomes. The study therefore raises questions about whether existing guidelines for evaluation are sufficient or appropriate when applied to complex interventions.

It would be easy to criticise the Stop Stroke team (including me) for not producing a more defined protocol, not hiring more experienced staff, providing better training, or for not continuing the pilot until all intervention components and outcomes had been tested. However, the findings suggest that there are a number of issues specific to complex intervention implementation and evaluation that make complex trials problematic. These include the influence of RCT methods on intervention design and its subsequent impact on the implementation process; and the relevance of the pilot evaluation in an environment where resources are limited and where routine practice, trial environment and even trial process changes over time.

#### *8.8.1. Improving the study protocol*

The study protocol used in the trial could have been more detailed with more clearly defined eligibility criteria and a more accurate power calculation at the outset. The term ‘pragmatic trial’ appeared to be used too readily, possibly to avoid addressing complex technical issues or ‘grey areas’ such as potential future problems in defining eligibility criteria. Clinical practice guidelines simply state that the protocol must be detailed and clear and do not encourage investigators to acknowledge ‘grey areas’ or prepare strategies for dealing with potential problems which are not yet fully understood. This possibly reflects the fact that lack of clarity in protocol decisions is thought to challenge trial integrity.

One protocol issue that could potentially have been improved prior to the start of the study was the inadequacies of the power calculation. Compared to previous complex

intervention studies (Chapter 3), Stop Stroke power calculations were more detailed than most since they were based on ‘real’ data appropriate to the population. Estimations were also calculated for each key outcome but these were still over optimistic. One explanation for this is that since the intervention components were dependent on the SLSR, the power calculation was limited by SLSR throughput. Starting with a base of 225 SLSR patients per year, the statistician calculated what would be possible to achieve within three years of funding. Unfortunately the yearly estimates of 225 patients per year were not sophisticated enough for the trial, since not all 225 patients were ultimately eligible for inclusion. In the case of Stop Stroke, these inadequacies were picked up within a year via the process evaluation and it was possible to compensate for under recruitment by widening the recruitment area and increasing the number of GP practices. The process evaluation provided the opportunity for the investigators to find novel ways to overcome challenges. However, given that most RCTs of complex trials are underpowered, as shown in Chapter 3, it might have helped to have had detailed strategies for monitoring recruitment and considered ways of addressing possible under-recruitment in the protocol.

#### *8.8.2. Improving the pilot*

In the case of Stop Stroke, most of the protocol problems only really emerged once recruitment had started but in a standard clinical trial it is not considered good practice to adjust the protocol once the trial is underway. Conducting *any* pilot study is unusual within a complex trial environment (see Chapter 3). However, resolving all protocol issues that subsequently emerged would have required an extended pilot study and there would have been no guarantee that an extension of the existing pilot would have unearthed or resolved protocol problems. Some issues such as the difficulty of



delivering the intervention to patients prior to discharge from hospital had emerged during the pilot but the solutions (to wait until all patients had been discharged) were not taken up in the interests of preserving a neat trial and ensuring that all participants received the same intervention regardless of hospitalisation status. In practice patients did not end up receiving the same intervention since it would have been impossible to recruit sufficient numbers if the trial had been restricted to patients identified within six weeks of their stroke. The trial methods had both defined the intervention and limited the uptake of pilot findings at the outset.

RCT processes and intervention quality may have benefited from a 'run in' phase in the first year. This might have helped resolve problems such as programming errors, allowed staff to gain experience in running trials and allowed them to develop a better understanding of the intervention and their roles in delivering and evaluating it. However, it is not clear where the extra funding for such a phase could have come from. It is unlikely that funding bodies would provide additional resources for a post-pilot 'run-in' phase prior to a definitive RCT.

Equally, because the environment, the 'real life laboratory' within which the intervention was delivered, was continuously changing, new problems continued to emerge throughout the study. Lack of continuity in staffing over the three years combined with the complexity of understanding the SLSR, the Stop Stroke intervention and trial process meant that solutions to problems that had emerged in the pilot phase were insufficient to address problems emerging later on in the main trial. An ongoing recruitment and training programme would have been needed to ensure that staff turnover did not have a negative impact on trial process or outcomes, something not possible within the limited resources.

### *8.8.3. Improving staff understanding and motivation*

A second problem that could theoretically have been avoided, concerned staff understanding and experience particularly in relation to recruitment practices. The administrators were hired on the basis that the intervention did not require technical expertise to deliver. However, their lack of clinical trial expertise may have contributed to poor understanding of trial methods (such as the importance of concealing from the data collection staff to which arms of the trial patients and practices had been allocated, or methods for rigorous monitoring). Complex trials often aim to influence outcomes over a longer period of time than in a clinical trial (over one or more years).<sup>87</sup> Thus in order to gain sufficient power, the recruitment and follow-up also take a long time (in the case of Stop Stroke three years plus one year follow-up). It would not have been possible to hire an experienced trial manager over this four-year period within the limited budget. In clinical trials it is possible to overcome such problems by conducting trials on multiple sites (multi-centre). However, while theoretically possible, conducting a multi-centre trial of a complex intervention such as the Stop Stroke intervention may have been even more difficult to operationalise. There have been few published examples of multi-centre complex intervention trials in the literature. For example, in the review presented in Chapter 3 only one complex trial was a multi-centre study.<sup>161</sup>

My role as process evaluator had an important impact on trial process and intervention implementation since it enabled me to uncover problems as they arose and to intervene to resolve them. It was not written into the protocol that it was my role to monitor recruitment or to provide support for staff and there is little guidance on the appropriateness of using process evaluation data in this way. Some researchers have acknowledged the benefits of participant observers making ‘practical contributions’ to the research environment,<sup>216,244</sup> and it is generally accepted that when using interpretive

approaches the researcher will have an impact on the research, a Hawthorne effect,<sup>216</sup> and is expected to acknowledge this through reflexivity.<sup>247</sup> However, there may be conflict when practical contributions are used within a study using a positivist research paradigm such as a clinical trial.<sup>117,250</sup> Clinical trials have strict rules governing the influence of the research process on trial outcomes, for example rules about the conduct of data monitoring and interim analysis while the trial is ongoing.<sup>65</sup> It is thought such monitoring/analysis may interfere with intervention delivery in such a way as to compromise trial integrity. Process evaluation findings may be just as powerful as interim outcome analysis in influencing trial staff (for example feedback about the patient's experiences of the intervention might increase or decrease staff motivation and disturb equipoise for those responsible for delivering the intervention<sup>105,106</sup>). Clearer guidance is needed on the conduct of process evaluation within the RCT context.<sup>117</sup> In the case of Stop Stroke, the process evaluation proved useful in ensuring that trial protocols were adhered to but this may also have had a detrimental affect on staff morale and motivation.

#### *8.8.4. Summary and limitations*

This analysis is limited in that it only reports on trial process during the first two years of the trial and it is possible that further issues will arise before the trial is completed. The interpretation of findings may also be limited by the methods used to collect data. This ethnographic approach incorporated the views of investigators with different levels of involvement in trial conduct and intervention delivery, those from differing academic backgrounds and with differing status within the academic setting. However, in-depth interviews were conducted only with junior staff since they were most closely involved with trial process. Interviews with other trial staff (for example the core group) might



have revealed other explanations for trial process. Differing interpretations of trial problems were identified in subsequent feedback. In particular, the PI and I2 both indicated that the analysis was quite negative. Although the investigation aimed to provide a balanced account of trial process, the findings may appear threatening to the study team, since some of the problems exposed may be interpreted as having been avoidable. However, I would reiterate that the investigators followed recommendations for the conduct of clinical trials and that the problems encountered were largely a consequence of applying RCT methods to a complex intervention rather than attributable to individuals.

The problems of interpreting these data have already been acknowledged in Chapter 4. However, despite these limitations, this analysis presents a novel insight into the problems of conducting a complex trial and the potential of process evaluation for uncovering such problems and in resolving them. The use of qualitative methods embedded within RCTs is discussed further in Chapter 10. In the next chapter, I discuss the impact of the intervention on patients' understanding and experiences of secondary prevention.

## **Chapter 9. Understanding how the intervention works**

In this chapter I investigate the use of qualitative methods alongside RCTs, using in-depth interviews with stroke patients to understand how the intervention might potentially influence outcomes.

### **9.1. Introduction.**

Stop Stroke aimed to improve secondary prevention of stroke by influencing patient management in multiple ways. These included improving patients' awareness of secondary prevention and through encouraging the idea that stroke is a chronic disease. To achieve the first aim, it was hypothesised that advice needed to be evidence-based but also, targeted to the individual patient. To achieve the second aim, it was hypothesised that multiple strategies were needed. These included explaining the links between stroke and the individual's underlying risk factors; providing continuity between hospital and community providers; and providing secondary prevention advice in an ongoing manner at a number of time points. Thus intervention design was at least partially influenced by theoretical ideas generated from qualitative and quantitative research.<sup>34,124,214,215,344</sup> However, in Chapters 6 and 7, I demonstrated that intervention development and delivery were also influenced by social, political and economic factors leading to deviations from original theoretical ideas and protocols. What has not yet been explored is whether these deviations have had any influence on trial outcomes.

In Chapters 5 and 6, I suggested that patients' experiences of secondary prevention were influenced by a number of factors including the organisation of secondary prevention services, their understanding of stroke secondary prevention, personal priorities and physical, psychological, economic and social barriers. In this chapter I consider how the

intervention influenced these (or not) and the subsequent implications for understanding outcomes.

## **9.2. Methods and participants**

A detailed investigation was conducted with a purposefully selected sample of 20 patients in the intervention arm of the trial. See Chapter 4, section 4.6 for a full description of the methods. The investigation included documentary analysis of what was actually sent to patients and professionals, linked with in-depth qualitative interviews with stroke patients and/or their carers to explore what patients received and the impact of this on secondary prevention.

Table 16 lists the characteristics of participants for this detailed investigation. Patients included those with a range of different risk factors and maximum variation of age at the time of stroke (below 65, 65-79 and 80+), gender, socio-economic (SE) group at the time of stroke, ethnic group and stroke subtype (haemorrhage or ischaemic). Patients were interviewed after their one-year follow-up interview for the SLSR so as not to interfere with the measurement of trial outcomes. For all those interviewed this was at least one year after the acute stroke event and at least eight months since the last ‘dose’ of the intervention plans had been sent.

It was already reported in Chapter 8, that not all patients were sent all three doses of the intervention and this was incorporated into the sampling frame so that dose response could be explored. For this sample, a total of 47 patient and 47 professional plans were sent out. Three patients/professionals were sent only one plan each; seven were sent two each and the remainder received all three plans.



Table 16. Characteristics of patient sample for detailed process evaluation.

Patient ID	Age	Sex	Ethnic group*	Socio-economic group**	Disability***	Stroke subtype	Practice no.	Practice type****	Plans sent	Risk factors*****
1	73	M	W	M	Mod/mild	Ischaemic	105	Small multiple	3	H, D, O
2	71	F	BC	M	Mod/mild	Ischaemic	80	Small multiple	3	H, D
5	83	M	W	NM	Independent	Unclassified	4	Small multiple	3	None
8	58	M	W	NM	Independent	Ischaemic	3	Small multiple	2	D
10	64	M	W	M	Independent	Ischaemic	114	Large multiple	3	H
11	69	F	W	NM	Independent	Ischaemic	91	Large multiple	2	H, D, A
12	78	M	BA	M	Mod/mild	Ischaemic	114	Large multiple	3	None
13	78	F	W	M	Severe	Unclassified	13	Large multiple	3	None
14	62	F	W	NM	Mod/mild	Ischaemic	88	Small multiple	3	O
15	71	F	BC	M	Independent	Ischaemic	109	Small multiple	3	H, D
16	78	M	W	M	Independent	Ischaemic	60	Small multiple	3	H, AF
17	75	F	W	NM	Independent	Ischaemic	90	Small multiple	2	H, AF

Patient ID	Age	Sex	Ethnic group*	Socio-economic group**	Disability***	Stroke subtype	Practice no.	Practice type****	Plans sent	Risk factors*****
18	76	M	W	M	Independent	Unclassified	60	Small multiple	2	H
19	74	M	W	M	Independent	Ischaemic	3	Small multiple	2	None
20	61	F	BC	M	Mod/mild	Unclassified	114	Large multiple	2	H, D, O
21	59	M	W	NM	Severe	Ischaemic	54	Small multiple	2	S, H, A
22	81	F	W	NM	Mod/mild	Ischaemic	32	Large multiple	1	S, AF
23	81	F	W	M	Mod/mild	Unclassified	35	Single	3	D, O
24	75	M	BC	M	Mod/mild	Ischaemic	60	Small multiple	1	H, D
25	78	F	W	M	Mod/mild	Haemorrhage	32	Large multiple	1	H

\* Ethnic group: BC Black Caribbean; W White

\*\* Social economic group defined using Register General Classification NM non manual groups (I, II, III non manual) and M manual groups (III manual, IV, V)<sup>273</sup>

\*\*\* Disability defined using the Barthel Index: independent (total score=20); moderate/mild (total score 10<20); severe (total score<10)

\*\*\*\* Practice type: single (only one GP); small multiple (multiple handed <10,000 population); large multiple (multiple handed > 10,000)

\*\*\*\*\* Risk factor abbreviations: H hypertension; D diabetes; AF atrial fibrillation; S smoking; A heavy alcohol use; O obesity.<sup>34,214</sup>

### **9.3. What patients received and the impact of this on patients' experiences**

At the start of each interview I introduced myself to the patient (and/or carer) and reminded them that they had been participants in a research study of a special intervention aimed at preventing stroke recurrence. Not all patients recalled that they were involved in the research. In these cases I provided more detailed explanations, including describing the purposes of the study, informing them that some people had been given special advice about preventing further strokes and others had not. I explained that they themselves might not have been aware of whether they had received anything special. At the time of the interview I knew the arm of the trial to which patients had been allocated but I did not specifically reveal this information at the start of the interview, unless the interviewee themselves indicated that they had received the intervention package.

#### *9.3.1. Patients for whom the intervention had no impact*

One of the commonly accepted assumptions of RCTs is that analysis should be based on 'intention to treat' (Rothman, p525),<sup>68</sup> that is, when conducting analysis, all those completing follow-up assessments should be analysed according to the arm of the trial to which they were originally allocated at the time of recruitment. This should be the case regardless of whether the participant changed arms during the trial (for example whether a control participant started taking the active treatment in a drug trial) or whether or not those in the intervention arm actually received the intervention. In the Stop Stroke Trial this intention meant that in analysis all those in the intervention arm had to be treated as if they and their GP had received the intervention plans and GP visits as outlined in the original protocol. I already demonstrated in the previous chapter that in implementing the intervention the trial team had difficulty adhering to the



protocol, that less than half of patients and GPs were sent all three doses of the intervention plans and that only just over half of GP practices in the intervention arm were visited by specialists. However, even when the intervention was sent to the patient (that is, the team did adhere to the protocol) it became clear from the interviews that some patients could not have benefited at all from the intervention. For three patients interviewed the intervention appeared to have had no impact on their experience of secondary prevention (patients 1, 18 and 22).

It was not always easy to establish whether patients had actually received the intervention since for most patients the intervention acted in subtle ways rather than having a life changing impact on their experiences. However, for at least one of the twenty patients interviewed no intervention packages reached the recipient. Since the intervention was delivered by post to the patient's home address there was an underlying requirement that a stable address could be identified. It is estimated that a substantial proportion of stroke survivors require ongoing care after stroke either through 'formal' support from health care services (just over a fifth from my analysis of trial monitoring data) or 'informal support' from friends and relatives.<sup>224</sup> For many of those patients, accessing support may also involve changing place of residence.<sup>345</sup> Place of residence appeared to have an important influence on intervention impact. By the time some patients had become settled (had a stable address) the period for delivering the intervention had already passed. For Patient 22, the intervention had no impact because she did not return home to her usual address after discharge from hospital, instead spending some months deciding on a choice of nursing home whilst living in hospital. The Stop Stroke team had sent her sole dose of the intervention (6-month plan) to the nursing home address she had provided to the SLSR at the 6-month follow-up

interview [Nursing home A]. However, Patient 22 had never taken up residence at this home and the plan was never forwarded on:

JR: You haven't received anything. You haven't had anything through the post like a pack about strokes?

Patient 22: No, unless it's gone to me home. It might have gone to me address when I wasn't there [sic].

JR: Your previous address. So you were in hospital for three weeks and you came here straight away after?

Patient 22: No, not straight away. I come and visit [Nursing Home A] first. And I didn't like it, I wouldn't go there, so I went back to [Hospital C]. And then ... [Nursing Home B] had a vacancy so I come and see them and they said to fetch me and show me and they did. And they showed me this room and everything and I said, 'Yes I like it,' so I was accepted in and I've been here ever since.

JR: So it took a bit of time going backwards and forwards from [Hospital C]?

Patient 22: That's right.

For other patients, receipt of the intervention was more difficult to establish. Despite considerable probing (about packages sent through the post, advice about stroke, advice from the hospital and information leaflets received from health professionals or other sources where patients had learned about their stroke) three patients reported having not received the intervention, with no obvious explanation for not receiving it. Nor was there a clear dose-response explanation since one of these patients (Patient 24) was sent only one plan, one patient (Patient 18) was sent two plans and the other (Patient 1) was sent all three. For Patient 18 the impact of the intervention may have been 'contaminated' by another research study he was involved in. He was taking medication for diabetes, hypertension and high cholesterol but was also taking part in the 'PROFESS' Trial, a pharmaceutical industry trial of a combined antiplatelet drug for stroke secondary prevention.<sup>346</sup> This trial involved Patient 18 having regular check-up

visits with his GP and taking a specific medication that he had been informed was to prevent further strokes. The following extract from field notes written up after the interview demonstrates how the PROFESS Trial had influenced his understanding of his medication:

He [Patient 18] was taking 7 different tablets plus some medication for the PROFESS Trial, which he described as his stroke prevention medication. This consisted of three tablets, one to be taken before breakfast, one after breakfast and one in the evening. He didn't think the other medication was for his stroke since he had been told this [the trial medication] was specifically to prevent him having further strokes. He showed me the special leaflet that came with it, with pictures of the different tablets and instructions on when to take them in large bold letters. This was not the normal drug advice that came with a tablet. His other tablets included Gliclizide for his diabetes, Ramipril to lower blood pressure and Simvastatin. He said he didn't have high blood pressure and hadn't ever heard of cholesterol. He hadn't been told what these medications were for and hadn't been given any advice about his stroke or his medicines either in hospital or since.

The procedures and marketing of the PROFESS medication as the 'stroke medication' had a strong impact on Patient 18's experience of secondary prevention and may have made all other attempts at secondary prevention including the Stop Stroke package seem negligible by comparison.

In three further interviews patients stated that they had not received the intervention but went on to describe having received information which they had received, that resembled advice provided by the intervention plan but which they were unable to produce when asked (Patients 5, 13 and 24).

### *9.3.2. The intervention as a source of information about stroke*

Despite evidence that the intervention had failed to influence some patients' experiences at all, for most, it appeared to have had at least some impact. The packs were most



commonly discussed as a source of information for helping patients to learn about the stroke event or stroke risk factors. However, the importance of different aspects of the advice varied from patient to patient. Advice about diet and physical exercise were most frequently recalled, possibly reflecting inadequacies of information sources on these risk factors through routine services.<sup>275,276</sup> Patients for whom the intervention had provided information discussed how it had informed them about what a stroke is, the tablets they had been prescribed for stroke, their risk factors (atrial fibrillation, blood pressure and cholesterol) and the limits within which their physiological markers of risk should be maintained. As anticipated, the information was deemed useful for different reasons. For Patient 23, the intervention plans were the first and only source of information about stroke that she had received:

Well I didn't know anything about strokes....So really, they did enlighten you as to what a stroke was and how it comes about, you know. (Patient 23)

For Patient 11, the information was not new but had helped to reinforce the advice given from health professionals at the hospital or from the GP:

JR: Did you get a package or anything, when you – after your stroke, that had sort of information about strokes?

P11: Oh yes, yes.

JR: You did.

P11: Yes.

JR: And what did you think of it?

P11: I read through it all, it was very informative, yes. You know, basically that sort of backed up what they verbally told me anyway in the hospital, in the outpatients.

For patient 10, the packs were useful not only in providing facts about stroke but also in providing guidance on prevention management.

JR: And did you find it [the intervention packs] helpful?

P10: Well you get to know things about yourself and what you should do and what you shouldn't do. And they explain the details of the stroke ... how the cholesterol works, they have graphs in there somewhere haven't they [patient shows JR his plan]. The blood pressures and all, they explain. ... with the arteries and the blood pressures, there you are. That's, they tell you what the different tablets you take.

Although some patients seemed to have little interest in secondary prevention and stated that they would not necessarily wish to receive any more information, none of the patients indicated that they were unhappy with what they had received, even in cases where they felt that the information was incorrect. It is well known that measures of satisfaction often have ceiling effects or reflect other patient characteristics rather than the ability of the intervention to meet patients' needs or expectations.<sup>347-349</sup> Thus, it is difficult to interpret whether patients' non-critical responses to questions about how useful the intervention was, represented satisfaction or simply reflected a ceiling effect on this type of questioning.

Some patients identified errors in the plans. For example Patient 16 identified typographical errors:

P16: They've spelt my name wrong on that one.

JR: Oh have they?

P16: They've put an E ...

JR: Is it right on the next one?

P16: No.

JR: No. Still the same, okay.

P16: And they've put the wrong postcode on.

Spelling mistakes were not the only errors identified and patients also pointed out problems with the test results presented in the plans. Documentary analysis of what exactly had been sent to patients revealed that only 5/20 patients were sent interventions with no errors at all (patients 10, 11, 17, 24 and 25). All other patients were sent at least

one plan containing errors. Errors included: simple formatting problems such as poor presentation of test data (6.0000001mmol/L instead of 6.0mmol/L), bits of text highlighted in grey, or medications miss-spelt; misdiagnoses of risk factors or contraindications for medication; omitted medications; advice that was confusing or inappropriate. Inappropriate advice included: misdiagnosing the patient as a heavy drinker (when SLSR data indicated that the patients' alcohol use was unknown); telling the patient to visit their doctor to check they were on the right medication (when SLSR data indicated that the medication was appropriate); or not telling the patient to take the aspirin they had been prescribed (because the SLSR question diagnosing stroke subtype had not been completed).

While the above problems primarily related to technical issues in intervention production and delivery, some patients also identified problems with advice not provided in error. For example some patients disagreed with the advice they had received about their risk factor management, such as recommending that patients should change aspects of their diet (cutting down on salt or fat). These patients argued that the advice was not applicable to them since they did not usually eat much salt or fat.

P17: It says here, 'You haven't cut down on salt or salty foods.' Well I don't take much salt anyway...

JR: So some of the things in here don't seem to be quite right?

P17: No

However, these disagreements and errors did not seem to have a large impact on whether or not patients found the plans helpful. Patient 17 said that she had read through the pack couple of times and that it had provided her with information about blood pressure and cholesterol and diet, despite her highlighting that she felt that the advice on diet was inappropriate. Wiles argues that trust plays an important role in the efficacy of prevention advice and patients did not necessarily lose trust in the



information provided even when they disagreed with what it said.<sup>276</sup> Patient 10 explained that since he understood that the intervention had come from the hospital he felt that the information provided was more credible and reliable than other similar sources that he might have been able to seek out himself (such as in magazines or newspapers). Thus some patients may have appreciated being given information about their strokes even if it did not tell them anything new and even when they felt that the information was not wholly accurate.

However, despite providing information and advice on a range of stroke secondary prevention topics, there were some factual aspects of stroke care that patients felt that the packs were unable to address. In particular they could not explain how or why the stroke had happened. For patient 23 there had been no definite diagnosis so she was still unsure as to exactly what had happened:

P23: So I mean, the unanswered question is, what happened to me? Just probably like a dizzy spell. And nobody could answer that because it didn't leave me with anything to go on, did it, really for them. I mean they give you a brain scan. And they can tell from that. But that was all fine.

Even when a stroke diagnosis had been made, for some patients, explanations of the mechanisms between the risk factors and development of the blood clot that caused the stroke were still not sufficiently clear.

P19: Well yes, the first thing is, do they definitely know, it's too late now, what caused it in the first place? What caused the stroke in the first place? Well they do, they say a clot of blood through the scan, there that's caused the trouble. But where did it come from? How did it come about?

The plans had attempted to address patients' queries about stroke causation through explaining that the acute event was linked to underlying risk factors and through providing tailored advice on risk factor control relevant to the individual. However, for some patients (including patients 19 and 23) who did not have any of the usual risk

factors (including hypertension, atrial fibrillation or diabetes), the plans were insufficient in helping them to understand why the acute event had happened.

### *9.3.3. Encouraging continuity*

A second key aim of the intervention was to try to create a sense of stroke as a chronic disease requiring ongoing monitoring and management. One of the strategies for achieving this was through providing the intervention at multiple time points. I have already demonstrated that due to trial requirements, only a minority of patients (approximately a third) were actually sent the intervention at multiple time points (in Chapter 8). Thus it might be expected that this component would fail to have had any impact. However, for some of those who did receive all intervention components (as originally intended) the intervention did appear to influence their understanding of secondary prevention. For example, Patient 23 discussed the intervention as something that was ongoing:

JR: Has anyone ever given you any written information since the stroke, about your stroke or about?

P23: I've got all the literature...yes, they send it often, don't they...what to do to prevent it and how to avoid it and what to do.

JR: Was it like a pack that you received?

P23: Yes it's a pack isn't it, in a plastic cover like.

JR: That's right yes.

P23: Yes. I've had two of them. They do send them at regular intervals I think, don't they?

There was evidence that the strategy to deliver advice in a more personalised way also encouraged the idea that care was ongoing. Personalised advice may have reassured patients that there were no aspects of care that they had missed out on or that needed to be improved. The plans provided reassurance for some patients even if the patient did not agree with the advice provided. For example, Patient 16 identified mistakes in the

plans he had received but explained, “It’s very satisfying when I know people have some interest in me”. This contrasted with the routine care he expected to receive from his GP:

Patient 16: The doctor, I go, I bet if I go in next month, as he asked me to, there will be a different doctor there. That’s the trouble. No continuity. Not that I’ve seen anything but good treatment but it doesn’t help the doctor. You know, I mean, he sees maybe 50 or 60 patients a day.

JR: Yes.

Patient 16: And he’s got to look up all their records.

JR: Yes. Each time.

Patient 16: Each time.

It seemed to be that patients felt that receiving some advice (even if not perceived as being completely accurate) was better than the usual care alternative (in other words, receiving nothing). Thus some patients appreciated the intervention even if the packs did not appear to have had a life-changing impact on secondary prevention

JR: Did the package say anything about anything else apart from what you eat?

P14: Well it probably did but I can’t remember.

JR: You can’t remember?

P14: No, that’s one of ... the head don’t retain. As I say, it don’t hold things long, you know.

JR: Do you remember whether you found it useful?

P14: Yes, I thought it was quite good really. I thought it was quite good because I thought it gives you an insight into something because people don’t tell you nothing. You know, when you go to these hospitals, they don’t tell you...

However, despite these examples of the intervention working as anticipated, the findings cannot be generalised to all patients. Patient 17 did not believe the intervention was personalised, while Patient 23 did not feel that the advice was relevant or personalised to her:



JR: Did this contain any information that was specifically about you, or was it just general advice?

P17: Well I think it was probably general. Although it says here, 'Personal Plan.'

JR: Did you, the information that they sent you, did you find it useful?

P23: Well I did read through it. And if it was necessary, if it applied to me, I would have – but not much applied to me because I wasn't, you know, damaged from the stroke, was I?

To a certain extent the influence of the plans may reflect the strengths and limitations of the SLSR as an intervention tool. Patient 23's stroke had been coded by the SLSR as 'unclassified' and all her risk factors had been controlled at the time of stroke. Thus it was difficult to provide explanations for what had happened to her, or to provide advice on how best to prevent further strokes. Equally, the packs included test results showing how the patient was progressing but tests were not conducted specifically for the plans at each time point and instead were based on patients' reports and existing tests. If a new test had not been done since the last SLSR interview then the same information would be provided at multiple time points. Without updated information the plans may have had limited influence.

JR: Do you think that this sort of thing [the intervention] can help, that it's important to have something like this?

P19: Yes but that [three-month plan] is the same as that [six-month plan].

JR: Right.

P19: There's no point in people giving you the same thing. But if the cholesterol had been taken and that had been done and everything had been tested, and then you see if it's made any difference, then you would know.

Simply providing the same advice time and again was not necessarily enough to persuade patients that monitoring was ongoing. Equally, the plans were only provided to patients over a maximum of the first eight months post stroke and this may not have been long enough to promote the idea of continuity. For most of those interviewed,

contact with specialist stroke services ended within a year of the stroke. The termination of intervention delivery coincided with this, possibly reinforcing the idea that stroke care had finished.

Patient 10: I've had one [a plan] now for a long time, I think I had two, I may even have had three. But that's long ago, back a long way, a long way ago... I didn't have any last year, I finished with Mr X [at the hospital] last year.

JR: Yes.

Patient 10: I think April or something, or May or something was my last visit to Mr [X]. He said, 'there is no point in coming back, you're okay.'

However, continuity in secondary prevention management was encouraged if patients had other ongoing activities, which reminded them of the stroke and the need for secondary prevention. A number of patients went to stroke groups run by voluntary sector agencies such as Age Concern, Time and Talents, other research projects and the patient-involvement group set up by the local stroke Modernisation Initiative described in the previous chapter.<sup>235</sup> These contacts may have unintentionally interacted with the intervention to influence secondary prevention. Patient 19 described how his participation in the patient-involvement group had encouraged him to revisit his stroke intervention pack and to continue watching his risk factor management, which he would not otherwise have done. The Stop Stroke intervention had been discussed by another participant at the group as an example of something positive which had been provided after the stroke. The meeting had encouraged him to take another look at the packs and to take note of the secondary prevention advice.

JR: So did you come back and look at this?

P19: Because I was involved with the unit [user involvement group]... I've been paying a little bit more attention ...

JR: So you came back after this group and had a look at?

P19: Well yes, yes. I got them out and thought, 'Oh I'd better read what those 'Keeping Well Personal Plans,' are for.

Patient 19 discussed how after reading the packs, he had realised the importance of cholesterol control in preventing further strokes and consequently had started to take more notice of risk factor control strategies.

P19: When I got this 'Keeping Well After Your Stroke Personal Plan,' up to now I haven't taken a lot of notice of it but when I did read about the – where are we – the cholesterol tablets, these [patient shows JR the cholesterol advice sheet].

JR: This one here, the cholesterol.

P19: Yes, the cholesterol ones, I didn't really understand what they actually did but they're just as important, more than some of the others I take.

It was the interaction between the packs and the user involvement group that appeared to encourage continuity in risk factor management rather than the intervention alone. Without the user involvement group meeting and without the intervention having been discussed at that meeting the plans might not have been used.

#### *9.3.4. Patient empowerment*

The final theme that emerged from the interviews concerning the influence of the intervention on patients' experiences of secondary prevention, I have termed 'patient empowerment'.<sup>xi</sup> In this analysis I use the term in relation to responsibility and control and refer to the patient's ability to take responsibility for their own secondary prevention management. Thus the impact of the intervention on patients' choices, behaviours or actions related to secondary prevention is explored.

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<sup>xi</sup> Empowerment is a contested construct and has been used differentially over the past decades in relation to a range of social and political agendas. Historically it was used to refer to financial resources, but more recently has been used in relation to consumer choice.<sup>350</sup> Within consumerist models of healthcare, empowerment is often used to refer to user oriented services, responsive to users' needs.<sup>351</sup> Recent health policy is based on the principle that poor health is a consequence of individuals being 'dis-empowered', the assumption being that they can subsequently be 'empowered' through individual or social intervention, to enable them to take responsibility for their own health concerns.<sup>254,255</sup>



It was difficult to establish through interview whether the intervention had had any kind of direct impact on patients' choices, behaviours, or actions in relation to risk management strategies. In most cases patients did not, or could not distinguish whether the advice that had triggered their actions was provided by the intervention plans or by other sources. This was further complicated by the fact that most patients saw the plans as having come from the hospital and did not distinguish between the impact of the intervention and that of other health services or activities they were engaged in.

However, there were examples of patients developing new strategies since the stroke that fitted with recommendations for optimal secondary prevention and there were some patients who related their actions to the intervention. Such strategies included developing new exercise routines or making alterations to diet: cutting down on sugar or salt or eating substitutes for these; drinking less coffee, less alcohol or more water; eating foods marketed as cholesterol lowering; cutting down on saturated fat from red meat; or buying low-fat dairy products. Since diet and exercise awareness were most strongly attributed to the plans it is possible that they also had an influence in encouraging patients to take responsibility for risk factor management in these areas:

JR: With this information that you've had, did you, did it make you do anything different after you'd read it?

P2: Oh yes. It make me exercise and drink more.

JR: Really? That's good.

P2: I drink a lot of water.

JR: Is that drinking water or is that drinking alcohol?

P2: Water. I never smoke and I don't drink...about the stroke, I mean about the diabetic...but I'm never interested in that and since I know it don't agree with me, I don't do it. And... I just keep away from that.

JR: Yes, that's the best thing, I think.

P2: My drink is water and tea and I drink the diabetic drink but sometimes it tastes sweet, Coke and those, you know. I drink the diabetic drinks. And, what do they call it? Keep fit yoghurt.

In the interviews presented in Chapter 5, the local environment and fear of crime were found to be barriers to patients leaving the home either to exercise or to access health services. The environment was also identified as a barrier to secondary prevention in these interviews but some patients with disabilities had developed novel strategies to overcome these barriers. These included, walking around the home or up and down the corridor outside of the flat to exercise, or in the case of Patient 25, climbing the stairs in her block of flats by the rubbish chute which did not require her to cross busy roads. Other examples of patients taking responsibility for their own risk factor control included monitoring body processes. Two patients kept records of their own blood pressure, one of whom had bought his own device which he demonstrated to me during the interview. He explained how he used it to monitor his own blood pressure:

Patient 10: I check it myself, I take it regularly.

JR: Oh right.

Patient 10: It's a little one you put on your wrist, you know what I mean...I check it every day.

JR: You check it every day, do you?

Patient 10: I check most days, most days, yes.

JR: Right.

Patient 10: Well it varies, as you know, the blood pressure goes up and down doesn't it?

JR: Yes.

Patient 10: One day it's high, next day it's down...that's how it goes. But when they expect it high, then it's low.

JR: So you checked it today did you?

Patient 10: I haven't checked it today. I usually check about 4 o'clock in the afternoon, at the same time every day.

Checking one's own blood pressure was one of the suggestions in the blood pressure advice sheets but Patient 10 was unclear as to what had prompted him to buy a machine or start his own monitoring. When asked about the level at which he was aiming to keep his blood pressure he explained that his GP had recommended less than 150 (systolic blood pressure) but he had also been told 140 (as it stated in the plan). However, he attributed this advice to the doctors at the hospital and not the plan specifically.

The plans themselves were also used as a means of monitoring blood pressure, a record that patients could use if questioned about how they were progressing.

JR: And you're on tablets for your blood pressure as well. Do you know what your blood pressure is?

P19: Wait a minute, it's in one of these [intervention plans] and it's accurate. I think I used to keep – in here. No I can't remember now. [the patient gets out one of his secondary prevention plans.] It was 136 – no but this is months ago.

JR: that was your blood pressure in June last year?

P19: Yes. Oh crumbs. Because when I was going regular, I used to write it down on me...but they said it was alright.

JR: It was okay, was it?

P19: Yes.

However, the plans only seemed to encourage patients to take responsibility for risk factor control in areas where they did not need to seek contact with medical services. There were a number of different scenarios in which the intervention plans advised patients to seek medical advice (see Chapter 7, Tables 13 and 14). Twelve patients were advised to seek medical consultation from their doctor in their three-month intervention plan, including for advice about their medication or for cholesterol monitoring. Fourteen patients were advised to seek medical consultation for the same reasons in their six-month plan. However, only one of the 20 patients interviewed indicated that (s)he had



sought medical advice as a result of the plans<sup>xii</sup>. One explanation for patients not discussing the plans with their GP may have been that they perceived that the GP would already know of any problems with their health and thus would contact them directly for a consultation if necessary, or would automatically raise any problems should the patient routinely visit the surgery.

JR: You haven't ever taken it [the plan], you haven't ever shown your doctor or anything like that?

P25: No. If he asks when he comes over, it's there for him to look at.

In Chapter 6, I demonstrated how both patients and professionals assume continuity of information between primary and secondary services, despite gaps in service provision. I also demonstrated how 'medical authority' can prevent patients from challenging professional decisions. Such influences may have had an impact on patients' interpretations of recommendations to seek medical advice provided in the plans.

The one patient who did seek medical advice about his tablets (Patient 16) may have been different from the others. He was both highly motivated to take responsibility for his own risk factors (changing his diet, cutting out alcohol and walking at least a mile daily) and had atrial fibrillation (an ongoing heart condition for which specialist clinic follow-up is provided, unlike other stroke risk factors, see Chapter 5). According to the RCP guidelines Patient 16 should have been prescribed warfarin since the register data indicated that he had no contraindications for the drug. The intervention informed him that he was not taking any secondary prevention medication for his atrial fibrillation and encouraged him to check with his GP. Patient 16 used the plan as a reason to question his GP about the treatment he was taking.

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<sup>xii</sup> In a study of advice to seek cholesterol testing for heart disease, a letter to patients achieved a check up rate with GPs of 81%.<sup>352</sup>

P16:...they wrote on it, 'You're receiving no medicine for your heart. Go to your doctor ... for your heart condition,' you see. So I thought I can't go to my doctor and say that, 'you're not treating me right.' So anyway...I showed him and he said, 'What's this?' And I said, 'It's from [Hospital X], it's a record of my illness and it shows that I'm not getting anything for my heart.'

However, he explained that his GP had informed him that his medication was appropriate. Yet according to SLSR data, by the six-month follow-up visit the patient had been prescribed warfarin (the RCP optimal treatment). Although this is an isolated case it does suggest that the plans may have some capacity to 'empower' patients to challenge medical authority and this may in turn have influenced risk factor management.

One of the key aims of the intervention was to provide secondary prevention advice to those who were less mobile as a result of the stroke and would not routinely receive it from health services. Thus the intervention was designed to be used by carers as well as patients. For Patient 20, this strategy appeared to work since her daughter who had some clinical training, was able to use the intervention to explain to her about secondary prevention:

JR: So, you didn't receive any packs that were specifically for you and about stroke?

P20: Yes, I received a packet when I've just come out, yes.

JR: Oh okay.

P20: I did receive one. And it show you everything like your heart rate and everything. I don't know, I think it must be somewhere upstairs. This is the last one I get a couple of weeks ago. So I did receive a big package.

JR: That was shortly after your stroke, was it?

P20: Yes, yes. And it showing that – like my blood pressure should be checked quite often and things like that, you see.

JR: Was it useful? Do you remember?

P20: It was useful to me because I could see – my daughter was, she's a nurse too, you see, my daughter but she has so many different job that she don't know which one to keep. So she also explain it to me.

There were some patients for whom the intervention had little chance of 'empowering' them to take responsibility for risk factor management. Patients with severe disabilities who were living in residential care (Patient 13) and those who had full time carers at home (Patients 21 and 24) were dependent on their carers for secondary prevention management. For these patients the ability of the intervention to influence secondary prevention strategies depended on the carer prioritising secondary prevention, which did not always happen. For example, Patient 13 had psychiatric problems and was dependent on her nursing home staff to organise monitoring of blood pressure and cholesterol, provision of food and administration of medication. She was also bed-bound and thus unable to engage in even light forms of physical exercise for prevention. The nursing staff explained that only experienced psychiatry specialists could deal with her health concerns. At the time of visiting her, the manager of the nursing home explained that in the context of her psychiatric illness she felt that stroke secondary prevention was relatively unimportant.

Similarly Patient 21, who was cared for by a friend, also had little individual power to influence his own secondary prevention management. He had been a heavy smoker and an alcoholic at the time of stroke and was homeless, living either in the park near his friend's house or in hostels. The stroke had left him severely physically disabled and unable to speak. On discharge from hospital he had moved in with his friend and now lived on a bed in the living room (he was in bed at the time of interview). This interview was not recorded but the following extract from field notes taken during the interview illustrates the lack of 'power' the patient had over aspects of his secondary prevention management.



I asked [the carer] whether [Patient 21] smoked. Throughout the interview [the carer] had chain smoked, in fact the room was so smoky at one point my voice started to go and my eyes started watering as I tried to suppress a cough. I can still feel it in my throat an hour later! [The Carer] said that [Patient 21] used to smoke before the stroke but since the stroke he [the carer] had refused to give [Patient 21] any cigarettes, like with the alcohol. He said [Patient 21] would look over and see him smoking and would sometimes gesture for a cigarette but [the carer] always refused. He said [Patient 21] had given up for a year now and he didn't want to let him start again. I asked [the carer] if I could speak to [Patient 21] about it. I went over to the bed and asked [Patient 21] whether it was OK that he wasn't allowed to smoke anymore. He gestured 'thumbs up'. I asked if it was OK not drinking so much and [the carer] said 'you feel better not drinking and smoking don't you?' [Patient 21] gave the thumbs up.

Although the plans may have helped the carer of Patient 21 to take responsibility for aspects of the patient's secondary prevention management (through informing him of the medication he needed and encouraging him to prevent his friend from smoking), it had done little to empower Patient 21 himself to make choices about alternative treatments, to take control of his own management or to prevent him being at risk from passive smoking.<sup>353,354</sup>

For those who had less severe physical disabilities but no carer assistance the plans also appeared to have limited use in the context of empowerment. Patient 12 had less severe disabilities (as measured by the Barthel Index) but was not only housebound but also unable to make phone calls since he could not afford credit for his mobile phone and the landline had been disconnected. He had fallen out with his family and had no way of contacting his GP practice to explain why he was unable to come for a check up. When I asked him about the intervention package he explained that he had read the information but had not found it helpful since he felt that he needed personal contact from health services.

JR: So do you feel a bit that the information is not that helpful because you can't get to see the doctors anyway?

P12: No, the question yes is that, the most knowledge you told people about their various type of illness, they should – either the patient to see them, or their doctors should make sure that they see to the needs of these people, how they could improve their condition ...Now, the follow-up should come from the proficient people like the doctors, the specialist and so forth and they should then provide adequate means or contact, you see.

Although he had appreciated that the intervention was designed to help him manage his own secondary prevention, he did not feel that this was an adequate substitute for the clinical care that he could not access. Consequently he did not find it helpful.

#### **9.4. Discussion**

In this chapter I have presented findings from analysis of patients' experiences of using the Stop Stroke intervention. These findings, together with those from Chapters 7 and 8 on intervention development and implementation will help in understanding the eventual success or limitations of the intervention in influencing outcomes.

However, before I discuss the possible influences of the intervention on patients' experiences of secondary prevention and on trial outcomes, it is important to consider the context in which these interviews took place. The interviews were solely with patients (and carers) and so interpretation of how health professionals had used or responded to the advice provided cannot be investigated (except where patients reported it had influenced their own experience). The timing of the interviews may also have limited my ability to investigate links between the intervention and subsequent patient actions. These interviews were more of a snapshot of patients' and carers' understanding of secondary prevention, which may change over time (as their symptoms change and as patients and carers are exposed to different services and

information sources). Since the interviews could not be conducted until the outcome data had been collected (to prevent contamination of trial outcomes), all interviews took place at least eight months after the date at which the last intervention plan had been sent. In this time patients may have taken up advice provided by the intervention but may not have been able to recall doing so. Certainly there were some patients (Patients 1, 5, 13, 18 and 24) for whom it was difficult to establish whether or not they had received the intervention at all. Memory and cognitive problems resulting from the stroke exacerbated difficulties with recall. Thus it is possible that the intervention had a smaller, greater or different impact on secondary prevention experience than could be uncovered through these interviews.

#### *9.4.1. How the intervention influenced patient experience*

Understanding the impact of the intervention is complex since risk management itself is complex and the intervention was not delivered within a vacuum. Although the aim was to identify ‘themes’ that might help understand intervention process and consequently trial outcomes, patients’ experiences varied according to the health and social context of individual lives. I have presented case examples of how individuals discussed the intervention and their secondary prevention management, which provide an insight into the processes by which the intervention influenced outcomes. The intervention had a subtle impact and thus it was difficult to disentangle experiences influenced by the intervention from those influenced by routine health services, other voluntary services and research studies. However, three key mechanisms emerged by which the intervention potentially influenced patients’ experiences of secondary prevention: through providing information about the stroke, underlying risk factors and treatment; through providing a sense of continuity in service provision, reassuring patients that



they were being looked after; and through encouraging or ‘empowering’ patients to take responsibility for secondary prevention.

It is well known in the literature that educational or information-based interventions are most likely to improve knowledge<sup>212</sup> and thus it is reasonable to speculate that for those who used the intervention as a source of information, it contributed to increased awareness of optimal secondary prevention strategies. Both patients and carers discussed how the plans had provided them with information that they had either not known before, or that reinforced information that they had received elsewhere. Poor information provision for patients after stroke has been consistently reported in the literature<sup>275,276</sup> and the intervention may go some way to filling this need.

However, it is also known that education based interventions are less likely to have an impact on other types of health outcome (such as adherence to medication, uptake of preventive behaviours or changes in bodily process).<sup>212,355</sup> This intervention tried to be more than just an educational package. It also aimed to encourage the notion that stroke is a chronic disease, through targeting primary care practitioners and improving continuity in service provision. The observation that some patients appreciated the intervention despite finding factual or typographical errors suggests that the information component was only one of a number ways in which it influenced patient experience. Previous studies have consistently documented that stroke patients have unmet needs and may feel abandoned with poor service provision once discharged to the community.<sup>356</sup> Yet few interventions to improve social support during this transition phase have had success (see the literature review Chapter 3). Providing systematic risk factor advice in the longer term may only have a subtle influence but may be better than opportunistic follow-up (usual care) in reassuring patients in this uncertain time.

Linking the intervention to a respected source (such as the hospital) seemed enough to ensure that patients did not lose trust in advice even when mistakes were obvious.

There was evidence from at least some patients that the intervention also had an influence on risk factor control through encouraging them to become more actively involved in their own risk factor management. Although some might argue that it is impossible to ‘empower’ people solely through education targeted at individuals,<sup>83,357</sup> individual patients discussed how the intervention had assisted or prompted them to take responsibility for aspects of risk factor management. There were enough individual examples of patients changing aspects of secondary prevention (their food or exercise routines, checking bodily process or even asking questions of GPs) to suggest that for some patients the intervention had some influence on their notions of responsibility and control, possibly through increasing awareness of what was considered optimal management or through increasing self-confidence (or self efficacy<sup>279</sup>) in their own abilities.

#### *9.4.2. Limitations of the intervention*

In Chapter 8, I identified a number of problems with intervention implementation (environmental changes, deviations from the protocol and the impact of the trial on theoretical development), which may influence the power of the intervention to influence outcomes, or the power of the study to detect differences in outcome. These problems had some obvious consequences. For example, not all patients were sent plans as intended and even when plans were sent, they did not necessarily reach the intended recipient. Problems of intervention delivery could have been overcome if time of discharge and place of residence had been taken into account (as recommended in

theoretical phase findings, Chapter 7) but may have been impractical in the context of this RCT (Chapter 8).

However, not all of the limitations associated with the intervention were necessarily the result of poor implementation. In Chapter 5, I discussed how the nature of stroke as a disease and organisation of services promote an experience of stroke, which focuses on the acute event. The intervention aimed to assist patients and primary care professionals in re-conceptualising stroke as a chronic disease through providing a more organised, personalised approach to the provision of secondary prevention advice, which it was hoped would encourage continuity. Despite the examples presented earlier, patients were not homogenous in their responses to the intervention and the interviews uncovered a number of social, health and service related factors that may have impacted on the ability of the intervention to achieve its aims.

Firstly, although for some patients the intervention provided reassurance that health care needs were being monitored, the process of producing intervention plans was computerised and there was no mechanism for 'active' intervention if inadequacies in management were reported. Patients' GPs were also sent risk factor information (via the professional plan) but there was no guarantee that they would take action if the information they received identified problems with patient management. Thus the intervention may have created an illusion of continuity for patients without influencing provider practice at all. The interviews uncovered one example of the intervention having had an influence on treatment prescribing. However, further investigation with GPs themselves would be required to gain a better understanding of the impact of the intervention on GP practice. To prevent contamination of the trial, this investigation is being withheld until trial outcome data collection has been completed (as discussed in Chapter 4).



Secondly, the ‘embodied’ experience of illness is complex and is influenced by a range of processes located both within the body (such as symptoms) and externally (such as health service intervention).<sup>239</sup> In the case of stroke, symptoms tend to be associated with the acute event and residual pain or explicit disability rather than underlying bodily process (such as high blood pressure or damaged arteries) which are hidden and thought to be symptom free (see Chapter 5). Despite attempts to make visible the links between the acute event and underlying bodily processes, the intervention had little power to change certain aspects of the embodied experience, such as the individual experience of symptoms. The intervention also had little power to influence stroke specialist service provision for treating such symptoms since it was targeted solely at primary care teams. Since intervention delivery finished roughly around six months post stroke, for some patients the intervention may have reinforced the experience of stroke as an acute event, rather than counterbalancing discontinuity in stroke services in the longer term.

Where the intervention did interact with health services, voluntary projects or other research studies it seemed to have a stronger impact. However, the patients who interact with these services may already have better access to secondary prevention management. Previous epidemiological analysis of the SLSR has demonstrated that patients who fit into health service ‘systems’ at an early stage are those most likely to benefit from services in the longer term.<sup>358</sup> Interviews with professionals have also revealed that healthcare professionals streamline patients through suitable services and that those who do not fit existing service templates may have reduced access to care.<sup>359</sup>

One of the aims of the intervention was to close the gaps in service provision for such patients. It was felt that those who do not benefit from existing service ‘templates’ might benefit most from the intervention. However, these interview findings suggest that the problems of intervention implementation identified in Chapter 8 may have

exaggerated rather than closed such gaps with those missing out on existing secondary prevention strategies also falling ‘through the net’ of intervention provision.

The one group for whom the intervention had clear limitations were those with severe physical and psychological disabilities. This does not mean that the intervention did not have the potential to influence patient experiences at all, since it could have been used by the patient’s carer. Other carer focused interventions have demonstrated improved patient outcomes.<sup>185</sup> If the Stop Stroke intervention improved continuity and awareness of risk management strategies for carers then this may have translated into subsequent management. However, we know from analysis of trial process (presented in Chapter 8) that no carer plans were sent in the first two years of the trial. Equally in the research presented in this chapter, none of the three carers of severely disabled patients interviewed, viewed secondary prevention as a priority in the context of the patients’ other health concerns. Thus the intervention was unable to ‘re-prioritise’ stroke risk management.

It is perhaps not surprising that the intervention had less influence for patients with severe disabilities given that theoretically it was not designed with these patients in mind (see theoretical development Chapter 7). Subgroup analysis of trial impact for those with different levels of disability could explore these issues further. The challenges of theoretical development and the influence of RCT design will be addressed more fully in the discussion presented in Chapter 10.

## **Chapter 10. Discussion and implications for complex intervention development**

### **10.1. Introduction**

This thesis has provided a novel insight into the methodological challenges of applying ‘gold standard’ RCT methods of evaluation to Stop Stroke, an intervention to improve stroke secondary prevention. A number of questions were investigated including: the use of The MRC Framework as a measure of quality in intervention development and as a practical tool for guiding research; how qualitative methods embedded within a RCT can be used to improve our understanding of complex interventions; and how social, economic and political processes influence the construction of medical knowledge in the context of a complex public health intervention.

The work used a range of qualitative methods that are standard within public health research but also used one, ethnography that is much less common. Ethnographic accounts have been used to understand the production of scientific knowledge in other areas of science, for example in the laboratory<sup>360</sup> and in medicine<sup>361</sup> but there has been relatively little investigation of the construction of knowledge within the context of public health. Ethnographic studies of public health interventions have focused mainly on understanding the outcome of interventions rather than the production of knowledge per se.<sup>113,116</sup> This investigation was not straightforward and took approximately five years to complete, reflecting the lengthy and complex processes involved in the development of public health knowledge.

The research has raised a number of questions for complex intervention development, including questions about the benefits and limitations of the MRC Framework as a research tool; the social and political implications of adopting The Framework as a



measure of quality or research tool; the nature of scientific evidence more broadly; and the use of qualitative methods in intervention development and evaluation. In this final chapter, I discuss these issues and implications for future research and complex intervention development.

## **10.2. Application of The MRC Framework**

In Chapter 1, I described how I became interested in The Framework as a result of its popularity and at the time I had hypothesised that this was because it was a groundbreaking tool, a methodological ‘revolution’.<sup>93</sup> I had assumed that it would transform the way research studies were designed and in the process improve our understanding of the workings and outcomes of complex interventions. However, as the thesis has evolved, the practical uses of The Framework have become less clear, leading to questions about its revolutionary status and its ability to enhance our understanding of complex interventions. I now discuss The Framework, firstly, in relation to the practical benefits and limitations of using it as a research tool; and secondly, in relation to the broader social and political consequences of its publication.

### *10.2.1. Benefits and limitations of the MRC Framework as a research tool*

In this thesis The Framework was used as a research tool in two contexts: i) as a tool for defining and improving quality in intervention development; and ii) as a practical tool for guiding intervention development. The benefits and limitations of using The Framework in these ways are now discussed.

#### *10.2.1.1 Defining and improving quality in intervention development.*

In Chapter 3, I attempted to investigate the relationships between theoretical development, methods of evaluation and study outcomes. The MRC Framework was used both to guide search strategy and to devise quality criteria to evaluate theoretical and methodological quality. I used The Framework as a tool for evaluating a range of complex intervention studies for which current critical appraisal tools might be insufficient (since most studies would have failed to fulfil appropriate criteria). It was certainly possible to categorise interventions according to the development strategy adopted, as well as the evaluation strategy (more usual in critical appraisal), albeit not strictly into the four developmental phases outlined in The Framework. Thus the quality criteria developed may prove useful in defining and categorising interventions according to the theoretical assumptions used. It would then be possible for critical appraisal guidelines to incorporate such criteria into their recommendations for complex intervention evaluation. Since so few of the studies were classified as being theoretically and methodologically 'well developed' when judged against these quality criteria, it is possible that the observed lack of success of studies to demonstrate efficacy results from poor theoretical or methodological rigour. By defining standards for development, The Framework could enhance the outcomes of future research studies.

However, the MRC Framework has a number of potential limitations if used as a measure of quality in complex intervention development. Firstly, the definition of complex intervention is vague. Therefore it is not clear which sorts of intervention should be judged using these quality criteria. In the literature search presented in Chapter 3 (that based search criteria on MRC definitions), most of the interventions identified were not relevant to HSR or public health. I have already discussed how health promotion specialists have argued that the nature of complexity stems not from

the disease group or intervention components but from the ideology underpinning the intervention (Chapter 2). While I would not limit the definition of complexity to one or the other, I would argue that many different layers of complexity exist and that a clear understanding of these layers and how they relate to the intervention of interest is needed before recommendations can be made about appropriate evaluation strategies. Failure of the MRC Framework to at least consider the different challenges posed by different layers, or multiple layers of complexity before defining good practice (quality) in intervention development and evaluation must be seen as a limitation.

It is also debatable whether the MRC recommendations for intervention development and evaluation are the most appropriate indicators of quality. Findings from the systematic review suggest that even when RCTs are more rigorously developed (according to MRC phases), there is no apparent association with outcomes. The only significant findings suggested that: a) excluding non-RCT designs excludes most prevention and community-based studies; and b) if a RCT is conducted, the study has less chance of demonstrating success. Contrarily this finding supports previous arguments that RCT methods are inappropriate for evaluating certain types of complex intervention.<sup>8,88</sup>

The need for better theoretical grounding of interventions is particularly controversial within HSR, since it is a discipline which has typically been thought of as atheoretical.<sup>103,362</sup> While those from psychological or sociological disciplines might think it essential and intuitive that research (and intervention studies in particular) are strongly grounded in established theory,<sup>42,329,362,363</sup> others argue that understanding process is neither necessary nor appropriate.<sup>332</sup> It has been argued that until there is evidence that theoretically driven interventions are superior to a theoretical interventions, theoretical grounding should not be used as a marker of quality.<sup>331</sup> The



lack of association between theoretical development and outcomes of the 67 studies included in the systematic review may provide support for this argument.

While demarcating explicit modelling and exploratory phases may bring some benefits in terms of planning and obtaining funding, attempting to demarcate these phases may be problematic as a measure of quality. Both in the published studies (Chapter 3) and in the development of Stop Stroke (Chapters 5 and 6), it was difficult in practice to draw distinctions between the theoretical, modelling and exploratory trial phases. In terms of the intervention studies already published, this may reflect the fact that authors or publishers do not recognise (or have not in the past recognised) the importance of describing developmental work. A recent survey of pre-trial testing for complex intervention trials concluded that many trial investigators do conduct preparatory work including exploratory trials but simply do not report it.<sup>213</sup> In the context of Stop Stroke the first three phases were not distinct. Progression through the phases was cyclical rather than linear, with different phases overlapping and one phase merging into the next. It was also very difficult to implement a meaningful exploratory trial phase given time, resources and the nature of the intervention (Chapter 7).

To summarise, the MRC phases were a useful guide for investigating and critically appraising studies of psychosocial interventions in stroke care, particularly since other critical appraisal frameworks might not have been appropriate.<sup>125,340</sup> However, given the lack of clarity in defining complex interventions, current publication priorities and the difficulty of operationalising distinct phases of development, the limitations of using The Framework phases in defining quality need to be recognised.

#### 10.2.1.2 Guiding intervention development

My original hypothesis about the agenda of The Framework was that it was designed to help in guiding the development of new interventions. In the first publication of The Framework,<sup>1</sup> the authors stress that it is designed for those who are considering evaluating complex interventions. They go on to state that the main purpose of The Framework is to identify the unique challenges of complex intervention development and to ‘suggest some strategies for addressing these issues’ (p1).<sup>1</sup> Since its publication, there have been a number of studies that have reportedly used The Framework in this way (to guide development).<sup>3,121,364</sup> Two of these reported that The Framework was ‘helpful’, although neither study has completed its evaluation so the impact on intervention success or interpretation of outcomes is not yet known.<sup>121,364</sup>

The MRC Framework was also reportedly used to guide development and evaluation of the Stop Stroke intervention,<sup>365,366</sup> yet findings presented in Chapters 5, 6 and 7, suggest that this was not strictly true. In practice, it provided little guidance. Firstly, as noted in Chapters 1 and 7, design of study methods for developing and evaluating Stop Stroke pre-dated publication of The Framework. The Framework did not assist in guiding choice of methods in this phase (the team had already decided to use a mixed methods approach), nor did it provide any guidance on how to interpret ‘theory’ in the modelling phase of development. Eccles et al. have recently produced guidance on how to choose the most appropriate theory in intervention development (in other words practical guidance for the modelling phase)<sup>329,367</sup> but such guidance is not included in the MRC Framework.<sup>1</sup> Thus although The Framework could be said to have *refined* Stop Stroke development methods or provided post-hoc justification for the approach, it could not be described as having guided them.

It is not clear whether our team's decision to conduct a pilot evaluation was guided by MRC recommendations for an exploratory phase. A pilot evaluation was not explicitly outlined in the original research protocol for Stop Stroke, suggesting that The Framework may have influenced the decision to include this phase. The PI also confirmed that The Framework was influential in the exploratory trial phase in his feedback on the research findings. However, whether influencing the decision to include an exploratory trial constitutes 'guidance' is questionable, particularly since the pilot evaluation did not meet many of the recommendations for the exploratory trial included in The Framework. In the Stop Stroke pilot evaluation, possible variations in intervention delivery were tested (as recommended in The Framework) but qualitative methods were used to evaluate the impact of these variations rather than testing the main trial outcomes (Chapter 7). Other recommendations of The Framework such as ensuring that intervention delivery is standardised, investigating the comparative arm, or investigating sample size were not tested in the pilot phase.

Nor did The Framework assist in addressing the difficulties of applying RCT methods to complex interventions in the definitive RCT phase. Although the authors identify challenges for RCT evaluation (recruitment, consent, blinding, statistical power and choice of outcomes), The Framework does not provide guidance on how to address these challenges. Nor does it provide guidance on how to address challenges related to funding, staff continuity, protocol deviations and data monitoring (which in Chapter 8 were shown to have a significant impact on the potential of the intervention to influence outcomes). Complex intervention studies continually report under-recruitment in trials<sup>233</sup> yet no criticisms of current methods for producing power calculations or recommendations for strategies to obtain additional funds to extend recruitment are presented. There was an underlying assumption that the exploratory trial phase would



have uncovered all such challenges and that they would be addressed prior to embarking on the main RCT. In practice, The Framework provided little guidance for evaluation, simply outlining standard RCT evaluation rules.

### *10.2.2 Social and Political implications of using The Framework*

Beyond whatever practical value The Framework may have, adopting it as a measure of quality, or tool for guiding intervention development is likely to have broader social and political implications. Two potential consequences are discussed below: i) consequences for the development of knowledge relating to non-pharmacological interventions; and ii) consequences for researchers using mixed methods approaches in medical research.

#### *10.2.2.1 Consequences for the development of knowledge relating to non-pharmacological interventions*

Adopting the MRC Framework as a research tool addresses calls for more RCT evidence to support the use of non-pharmacological interventions (for example, in rehabilitation research).<sup>57,73,75,79</sup> Given the dominance of the evidence based medicine paradigm, policy makers and providers require an evidence base to recommend and fund complex interventions. By encouraging developers of complex interventions to use RCT methods in evaluation it could be argued that an aim of the authors of the MRC Framework is to increase the evidence base (as defined by RCTs) for these types of intervention.

The Framework is novel in its contribution to the evidence-based medicine debate in that it explicitly attempts to address the problem of interpreting clinical trial findings. Such problems are well recognised in the literature.<sup>42,60,368-370</sup> By setting out the

theoretical and modelling phases, the MRC Framework not only acknowledges that interpretation of findings can be difficult (whether the intervention is successful or not) but also recommends methods for overcoming such difficulties. The Framework proposes that a better understanding of theoretical process (in other words the mechanisms by which the intervention is intended to work) will facilitate interpretation of RCT evidence (p7)<sup>1</sup>. Analysis of the development of the Stop Stroke intervention suggests that although theoretical and modelling work were undertaken, the choice of intervention was not dictated by the results of this work. The modelling phase was used to identify how the intervention components could potentially influence outcomes (as recommended by The Framework) but in practice the intervention was not delivered as intended. Having a theoretical understanding of how the intervention could *potentially* work is not the same as understanding how it works in practice. The challenges for translating theoretical ideas into practice were also demonstrated in the ‘Dutch heroin experiment’.<sup>113</sup> This intervention sought to reduce rates of heroin addiction and was based on theoretical work and a pilot evaluation prior to its evaluation in a RCT. This work suggested that prescribed heroin could be a suitable treatment for users. However, the RCT failed to demonstrate any impact of the intervention on outcomes. Findings from the theoretical and pilot phase work were only partially able to explain the intervention’s failure. By contrast, an ethnographic process evaluation of implementation in the main RCT revealed that users’ attitudes to the prescribed heroin programme changed after the pilot study, creating recruitment and adherence problems that doomed the trial to failure. In this study it was the process evaluation rather than the initial theoretical or pilot work that helped to explain outcomes. As noted in Chapter 2, social scientists, including those who are proponents of RCT methods, have frequently argued for use of process evaluation to enhance interpretation of

findings,<sup>82,113,115,117,371,372</sup> something not included in the MRC Framework (an issue I return to later).

The MRC recommendation that complex interventions are evaluated using RCT methods also raises broader questions about what constitutes evidence in public health and HSR. This recommendation assumes that it is necessary to define particular methods to further medical knowledge. By contrast, Feyerabend argues that no single method or theory can be used to define what is or is not 'scientific' since this would inhibit scientific progress.<sup>373</sup> Unlike Kuhn, he suggests that scientific innovation is often accidental and thus argues for theoretical and methodological 'anarchy' (p11).<sup>373</sup> There has been considerable debate within the literature about existing hierarchies of evidence which place RCTs at the top of the hierarchy and define other methods either as producing 'lower level' evidence or discount them altogether.<sup>100,333,341,342</sup> As noted in Chapter 1, there are two versions of The Framework, one in which the authors specify that it is for guiding those embarking on RCT evaluations of complex interventions<sup>1</sup> and the other in which the authors do not distinguish the types of complex intervention study to which it should be applied.<sup>6</sup> Thus it is not wholly clear whether the authors intend The Framework to be applied to all complex interventions or only those for which RCT evaluation is considered to be appropriate. If The Framework is to be applied only to interventions for which RCTs are considered appropriate (for example medical, behavioural or educational models of intervention) then it would be unfair to criticise the authors for focusing on RCTs. However, if the authors intend The Framework to be applied to all complex interventions then focusing on the RCT as the sole method of evaluation may be problematic. The novel aspects of The Framework (theoretical and modelling phase guidance) do not help to address the criticisms of those who argue that it is inappropriate to apply RCT methods in evaluating complex



interventions. For example, The Framework does not give guidance on: how to include marginalised groups into intervention studies; how to address the problem of randomisation when no suitable control group can be found; or how to maintain a trial over a long period of time so that appropriate outcomes can be measured. If complex intervention evaluations are to be restricted to RCT evaluation, then this is likely to restrict both the types of interventions that are developed and the evidence that is subsequently produced.<sup>8,9,88,113,374,375</sup> As previously noted, dependence on the RCT method to define evidence does ultimately restrict the types of intervention that can be transformed into evidence.<sup>45,210</sup> If it is more difficult to conduct RCTs of population and preventive interventions, then a consequence of following the recommendations of The Framework could be that funds are re-directed towards those interventions which are situated within more easily defined communities (such as hospital departments), or those targeted at individuals (and consequently those which are ‘trialable’).

Proponents of RCT methods have argued that such criticisms are due to ‘misconceptions’ about RCTs and cite history of experimentation in social science to defend their preferences.<sup>73,74,76</sup> However, in the context of scientific innovation, Feyerabend argues the opposite: historically it is only when scientists diverge from existing theories or methods that science can progress.<sup>373</sup> Enforcing one specific method such as the RCT or specific phases of development (as in the MRC Framework phases) may stifle rather than enhance progress and consequently inhibit our understanding of complex interventions.

#### *10.2.2.2 Consequences for researchers using mixed methods approaches*

If the MRC Framework did not provide guidance for Stop Stroke intervention development or evaluation, it begs the question, why do we (the Stop Stroke team)

stress that it did? I propose that this is because adopting The Framework has social and economic consequences for those using mixed methods, in other words, that it in some way encourages or legitimises the work of these researchers.

As outlined in Chapter 3, part of the appeal of The Framework amongst social scientists is that it is perceived to support a mixed methods approach. The Framework was not developed specifically for qualitative researchers but, since its publication, has been embraced by some researchers who use qualitative or mixed methods. Just as alternative medicine practitioners may seek evidence for their practices in order to “bolster their case” for funding,<sup>84</sup> so MRC support for using qualitative methods in intervention development may be perceived by qualitative researchers to enhance the appeal of qualitative methods to those who fund medical research. Having access to medical funds may be a particularly attractive prospect for qualitative researchers, since this research attracts far more funding than is available from more usual sources (the MRC research spend was just under £475 million in 2005 compared to the ESRC research budget of £77 million).<sup>376,377</sup>

Those who use qualitative methods may also view The Framework as having the power to enhance their authority as researchers working within a medically dominated discipline such as HSR. An example of the need for social scientists to bolster their social, rather than economic position is described by Balshem in her study of Project CAN-DO.<sup>378</sup> Project CAN-DO was a health education programme focusing on cancer prevention. The project was situated in a working class neighbourhood of an industrialised city in the USA and involved health educators giving community-based talks and providing leaflets to encourage people to change ‘unhealthy’ behaviours. Balshem worked on the study both as an anthropologist employed to gain an understanding of community resistance to health education and as a practitioner

delivering health education messages to the community. She describes how, when she first joined the study, the symbols of authority within her own discipline (a doctoral degree in anthropology) counted for little within a medical discipline. She explains how as an anthropologist working in an environment where only science was valued, she yearned 'to be seen as professionally competent' (p126-128).<sup>378</sup>

As we know, The Framework does not explicitly call for a mixed methods approach to either intervention development or evaluation but acknowledgement by the MRC that qualitative methods may be useful in the theoretical and modelling phases of development, may be seen to legitimise the researchers and research of those who use mixed methods.

### *10.2.3. Summary*

The MRC Framework was put forward as a research tool to improve complex intervention development and enhance our understanding of outcomes. This thesis has demonstrated that in practice it provided little practical guidance. However, if The Framework is adopted as a research tool, it may have broader social, political and economic implications. For example, if The Framework shapes the way clinical knowledge is constructed and restricts the type of knowledge developed, it may have implications for clinical practice, health policy and ultimately patient care. The Framework may also have broader implications for those who conduct research by legitimising a mixed methods approach that apparently bolsters the case for qualitative research and gives authority to the researchers themselves.



### 10.3. Embedding qualitative methods within RCTs

A second aim of this thesis was to investigate the potential uses of qualitative methods in intervention development and evaluation. As noted earlier, calls for the use of qualitative methods alongside or embedded within RCTs to inform intervention development (formative research) and to enhance understanding of outcomes (process evaluation) are becoming increasingly common.<sup>82,87,95,102,106,113,115,117,250,316,371,372,379-383</sup>

In the Stop Stroke study, an ethnographic approach was used throughout development and in evaluation. However, while proponents of qualitative methods usually outline the potential strengths of conducting such research, few have questioned the limitations of using qualitative methods in this way, or investigated the impact of qualitative research in influencing intervention development or clinical trial evaluation. I now turn my attention to these issues in the context of developing and evaluating the Stop Stroke intervention.

#### *10.3.1. Using qualitative methods to inform intervention development*

In this study, qualitative methods were used to investigate current secondary prevention practice to identify barriers to and facilitators of ‘optimal secondary prevention’ (Chapters 5 and 6). Important considerations for intervention development were uncovered. For example, findings from the in-depth interviews with patients demonstrated that the concept of secondary prevention itself had little meaning for patients (Chapter 5). These findings were essential in challenging a priori assumptions of the team about categories of good and bad patient, of ‘belief systems’ and communication ‘styles’ which subsequently proved to be of little use in understanding secondary prevention in practice. However, it was difficult through interview alone to establish the reasons why current services were insufficient, patients having limited

insight into the organisational and social mechanisms influencing secondary prevention delivery. Observational methods were helpful in developing an understanding of the process of secondary prevention delivery in the stroke clinic (Chapter 6) but it was not practically possible to observe consultations in general practice, the forum where secondary prevention advice and monitoring is most likely to be provided in the longer term. Thus if interventions are to be developed using qualitative methods, it is important to be explicit about the limitations of the specific methods used and generalisability of the findings collated.

Perhaps the biggest challenge for using qualitative methods to inform Stop Stroke intervention development was that qualitative findings were limited in influencing intervention choice (Chapter 7). This may have happened for a number of reasons including restrictions of time and funding (the one year allotted for the development phase was insufficient to collect and analyse data) but may also have reflected the lack of weight that qualitative findings have in influencing research decisions. Firstly, findings from the research phase of development were used to back up rather than inform intervention development. Secondly, recommendations for intervention design emerging from work in the theoretical, modelling and exploratory trial phases were not taken up, in the interests of preserving a methodologically pure trial (Chapter 7). The tensions between researchers from different disciplines using different epistemological approaches or research methods have also been reported elsewhere.<sup>82,89,378</sup> For example, in Balshem's analysis of Project CAN-DO, she discusses how authority and in particular, medical authority influenced the conduct and uptake of her anthropological work<sup>378</sup>. Balshem described how she found it difficult to reconcile the conflict of loyalties she experienced. On the one hand she wanted to develop an effective programme to improve people's health (the education programme). On the other,

conducting anthropological research that would subsequently be used by those in authority (health professionals) to exert this authority over others conflicted with her epistemological loyalties (p128).<sup>378</sup> Thus, it appears that the same social hierarchies and political agendas that influence whether qualitative research findings can be defined as ‘evidence’ for clinical practice also influence uptake of qualitative research findings in intervention development.

Researchers from disciplines supportive of qualitative methods have promised a great deal in terms of being able to improve our understanding of health services.<sup>82,102</sup> There is now pressure for them to deliver. However, such promises may have contributed to misunderstandings regarding the purpose of qualitative research.<sup>89</sup> For example, it may be assumed that qualitative investigations should be used simply as an add-on to more traditional methods for investigating health services or to fill in the gaps in our understanding that cannot be answered within a positivist paradigm. In practice, exploratory investigations, particularly those incorporating mixed methods, often result in posing more questions than they answer.<sup>216</sup> As others have demonstrated, there are challenges for conducting mixed methods investigations including difficulty synthesising findings obtained using different methodological or epistemological approaches.<sup>89</sup> In the case of Stop Stroke development, while the qualitative studies highlighted issues for current secondary prevention management they did not specifically define what the intervention should look like. Perhaps because of this, the influence of the qualitative findings in defining the intervention was further limited by broader social, political and economic influences (research priorities, expertise, resources, requirements of RCT design) and it is important to keep this in mind when interpreting outcomes. If the intervention fails to deliver, there is a danger that this will be attributed to the qualitative research failing to identify the ‘real’ problems and best



solutions. Such an attribution would require disregard for the ethnographic evidence reported here, which suggests that the impact of such evidence on intervention design is limited by social and economic factors which I have termed 'interference'.

This research is a case study and without other such in depth studies it is difficult as yet to generalise too widely. In the current scientific climate qualitative research still has relatively low 'status' in the evidence hierarchy. Presumably any status changes will take time and it will be interesting to see whether The Framework can have more of an impact in the longer term.

#### *10.3.2. Using qualitative methods in intervention evaluation*

A second use of qualitative methods in this thesis was in evaluating the intervention and the trial process through an ethnographic investigation embedded within the main RCT design. Qualitative methods are increasingly being recommended to enhance different aspects of trial evaluation, including to enhance trial recruitment, to improve participant understanding of trial process, to improve trial implementation and to understand outcomes.<sup>106,107,112,115,119</sup> However, what is less often considered is the influence of process evaluation on the trial itself. In a recent process evaluation of a school peer-led smoking intervention, Audrey et al. concluded that there was a Hawthorne effect, that is, that the evaluation interfered with the intervention.<sup>117</sup> Audrey et al. justified their methods by saying that the data obtained from the process evaluation provided a rich insight into the workings of the intervention; in other words they assumed that the end (having rich data) justified the means (conducting processes evaluation), even if the process evaluation ultimately contaminated the main trial. They argued that interference with the trial was acceptable since it would be easy to incorporate the interventional aspect of the process evaluation (a simple questionnaire) into the intervention, should it

prove successful. However, attaching aspects of process evaluation onto the intervention might not be so practical or appropriate for all complex interventions or all process evaluations. It is also perhaps naïve to assume that all process evaluations are either easy to implement or cost-free.

In the case of Stop Stroke, the process evaluation was specifically designed so as not to interfere with the RCT outcomes: patient interviews were conducted after outcome data had been collected and interviews with GPs will only be conducted at the end of the study. However, this does not mean that the process evaluation had no impact. In the Stop Stroke Trial the process evaluation appeared to have both positive and negative effects. While it helped ensure that the study investigators adhered to the protocol, it may also have demoralised staff or created problems where none previously existed.

Others have also demonstrated the powerful impact that qualitative process evaluations can have in influencing trial process.<sup>118,123</sup> In a RCT of a patient decision aid for prescribing of anti-thrombotic medication for atrial fibrillation, Thompson et al. ceased one arm of a three arm trial in which qualitative data had demonstrated that patients were experiencing distress as a result of the intervention.<sup>118</sup> Although qualitative findings may have limited weight in influencing the decisions of investigators regarding intervention design, potentially they could have a powerful impact on research practice. Riley et al. recently argued that monitoring committees should monitor and guide decisions relating to ethics and the influence of qualitative research on community intervention trials.<sup>123</sup>

Findings from the Stop Stroke study experience also raise particular questions about the application of ethnographic methods. I have already outlined in Chapters 4 and 8 some of the problems I experienced as a result of being both participant and observer in the same study. While being a participant allowed me to uncover trial limitations that might

not have been accessible to an outsider, it also raised questions about contamination, ethics and presented conflicts of interest. These ethical and methodological challenges are well recognised within the ethnographic literature<sup>216</sup> and recommendations have been made to ensure that participants are not exploited. These challenges apply equally within the context of a RCT.

#### **10.4. Implications and directions for future research**

Issues relating to the potential uses of the MRC Framework and the strengths and limitations of using qualitative methods in intervention development have some important implications for future research and practice.

One aspect of conducting lengthy developmental work and of incorporating mixed methods in intervention development and evaluation rarely considered, is the implication for funding complex intervention development. The authors of The Framework draw an analogy between development of complex interventions in public health/HSR and the pharmaceutical industry. However, I would argue that in practice there are few similarities between the two processes. Historically the phases of pharmaceutical trials were developed by the Food and Drug Agency (FDA) in the US and the European Agency for Evaluation of Medicinal products (EMA) in Europe to protect patient safety.<sup>70</sup> By contrast there is no explicit or implicit reference to patient safety within the MRC Framework. New drug therapies are also developed to make financial profit for the pharmaceutical industry, while complex interventions are often less marketable. Both differences have important implications for funding. Stop Stroke development benefited from multiple sources of funding and in the context of complex intervention development was relatively well funded. However, the true costs of intervention development and trial evaluation are likely to have been considerably



higher than the amount funded, particularly considering the number of staff involved throughout these phases and the dependence of the intervention on other research studies including the SLSR. The average cost of developing a new pharmaceutical therapy may be considerably more than for a complex intervention but so is the available funding (the average cost of developing a new drug is estimated to be over US \$800 million not including pre-clinical work).<sup>91,384</sup> Thus if future intervention studies wish to include multiple developmental phases, with or without the additional costs of process evaluation and process monitoring committees then increased funding will be imperative.

A second difference between pharmacological and complex interventions is the environment within which interventions are developed and delivered. Some types of complex intervention reflect social, political and environmental trends (as demonstrated by changes to the clinical environment during the Stop Stroke development and evaluation). Thus a long developmental 'phase' that might be feasible within the context of drug development is not necessarily appropriate for complex intervention development. The only way to shorten the developmental process would be to increase research turnover (for all phases) or to consider multi-centre evaluations of complex interventions. There has been limited work on exploring the application of multi-centre methods to complex interventions. Again, unless funding for the development of these types of intervention increases, it is impractical, if not impossible, to expect the methods for drug development to be relevant in the context of complex intervention development.

The findings also have implications for publication of research on complex interventions. I have already noted that developmental work, important for understanding intervention choice and interpretation of outcomes, is not always reported

in publications.<sup>213</sup> Without such information it is often difficult to understand how intervention components are chosen, how such components work in influencing outcomes, or how such interventions should be implemented if rolled out into practice. If our understanding of complex interventions is to change, a ‘cognitive shift’ is necessary in relation to the requirements for publication of findings from such studies.<sup>84,341</sup> There is a greater need for investigators to acknowledge the challenges emerging in the development of such interventions in order that the findings can be generalised and translated into practice. Unlike Eccles,<sup>329</sup> I do not think this requires set guidelines on how to choose theory. Rather, I would argue for more reflexivity by researchers in acknowledging how decisions about intervention choice are made and the motivations behind such choices. One way to achieve this might be through new standards for critical appraisal of complex intervention studies requiring authors to acknowledge and explain the theoretical work conducted and how this relates to intervention choice. Such guidelines could also provide recommendations for recording of intervention implementation so that future investigators or providers can see where the challenges lie and not repeat the same mistakes.

There is also a need to move beyond discussion of whether RCTs constitute the only appropriate research evidence and to realise that different types of complexity present different challenges. Rather than classifying all non-pharmacological interventions as ‘complex’ or ‘social’, it is important to consider what it is about the intervention that presents a challenge for evaluation. Strategies could then be designed to meet or compensate for such challenges, through conducting process evaluation for example, or through accepting that other types of evaluation are necessary to understand particular types of intervention (quasi-experimental, observational or qualitative designs). Arguing that non-randomised studies are inadequate on the basis of bias is an insufficient

exclusion criterion. It is clear from this thesis that choosing the RCT method can also bias the knowledge we have about complex interventions.

The MRC Framework was presented as a guide for addressing the challenges of applying RCT methods to complex intervention evaluation. However, through this thesis I have demonstrated that it provides limited practical guidance and may be more useful in legitimising than defining methodological choice. If RCTs are to be accepted as the appropriate method for evaluating complex interventions then further practical guidance is needed to enable researchers to prepare for potential problems, which might compromise study findings (such as problems with recruitment, staffing and data monitoring). Further guidance is also needed on how to incorporate process evaluation within the RCT context. Oakley et al have made some recommendations but these are limited to the context of educational interventions and were not applicable in the Stop Stroke context.<sup>115</sup> Ethnographic process evaluation, or experimental ethnography may provide enhanced benefits (in terms of understanding implementation and outcomes).

<sup>104,113,123,371</sup> Process evaluation monitoring committees may provide the answer to difficult ethical and methodological challenges but further investigation is needed in this area.<sup>123</sup>

One further area of research that may prove fruitful is in the area of non-complex or regular RCT evaluation. I have assumed throughout that the challenges presented in the Stop Stroke study are applicable only in the context of complex intervention evaluation. However, it may be that regular drug trials present similar challenges and would also benefit from process evaluation or mixed methods approaches.



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## **Appendix 1. SLSR analysis informing Stop Stroke development.**

This appendix includes the two published papers covering the SLSR analysis of patterns in management of stroke risk factors after stroke. These analyses also formed part of the theoretical phase research contributing to intervention development.

# Behavioral Risk Factor Prevalence and Lifestyle Change After Stroke

## A Prospective Study

Judith Redfern, MSc; Chris McKevitt, PhD; Ruth Dundas, MSc;  
Anthony G. Rudd, FRCP; Charles D.A. Wolfe, FFPHM

**Background and Purpose**—Stroke patients have a 15-fold increased risk of recurrent stroke, and those with  $\geq 1$  risk factor have a further increased risk of recurrence. Previous work found management of physiological risk factors after stroke to be unsatisfactory, but there is little information on behavioral risks within the stroke population. This study estimates behavioral risk factor prevalence after stroke and explores lifestyle change.

**Methods**—The study used data from the population-based South London Stroke Register, collected prospectively between 1995 and 1998. Main measures included smoking status, alcohol use, and obesity. Logistic regression was used to determine sociodemographic differences in these measures.

**Results**—At 1 year after stroke, 22% of patients still smoked, 36% of patients were obese, and 4% drank excessively. Younger patients, whites, and men were more likely to smoke, and younger whites were more likely to drink excessively. Women and nonwhites were more likely to be obese. Those living in hospital, nursing home, or residential care and nonwhites were more likely to give up smoking, but there were no other associations between lifestyle change and the sociodemographic characteristics of patients.

**Conclusions**—Different behavioral risk factors were associated with specific sociodemographic groups within the stroke population. After stroke, high-risk groups should continue to be targeted to prevent stroke recurrence. However, the relationship between sociodemographic characteristics and lifestyle change remains unclear; more research is needed into the process of change to find out how best to intervene to improve secondary prevention. (*Stroke*. 2000;31:1877-1881.)

**Key Words:** lifestyle ■ risk factors ■ stroke prevention

In the United Kingdom, Our Healthier Nation targets aim to reduce mortality from stroke by a third by 2010.<sup>1</sup> Stroke survivors have a 15-fold increased risk of stroke recurrence compared with the general population<sup>2</sup> and represent an important group to focus on if targets are to be achieved. Reducing recurrent stroke and death from recurrence is also recognized as a European priority, with targets set out in the Helsingborg Declaration.<sup>3</sup>

Patients with  $\geq 1$  clinical or behavioral risk factor have a further increased risk of stroke recurrence, and appropriate management of risk factors has been shown to be important for secondary prevention.<sup>4</sup> Recent work focusing on management of physiological risk factors in an inner-city multiethnic population found secondary prevention to be inadequate with high rates of nontreatment in patients for whom antihypertensive and anti-thrombotic therapies are appropriate.<sup>5</sup> Few data are available on behavioral risk factors within the stroke population.

One reason for focusing on clinical rather than behavioral risks is that lifestyle change is commonly assumed to be difficult to achieve, and secondary prevention interventions

often have limited success in reducing behavioral risk factors.<sup>6-8</sup> However, randomized controlled trials have shown that interventions to modify specific behaviors, such as physicians' advice to give up smoking<sup>9</sup> and excessive drinking,<sup>10</sup> can be successful, and the assumption that patients (elderly patients in particular) are unwilling to engage in health promoting behavior is not justified.<sup>11</sup>

Our Healthier Nation emphasizes the importance of empowering patients to make educated decisions regarding health and lifestyle and the importance of identifying high-risk groups to provide high-quality services. If stroke secondary prevention is to be successful, more information is needed about current management of such risk factors. This study aims to answer 2 key questions: What is the prevalence of behavioral risk factors following stroke, and what factors are associated with reduced risk?

### Subjects and Methods

The study used data from the South London Stroke Register, a population-based register that since 1995 has been collecting data

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*Stroke* is available at <http://www.strokeaha.org>



prospectively on first-in-a-lifetime strokes in patients of all age groups. Twelve overlapping referral sources are used to attain complete notification of such strokes in the study area, which comprises 22 wards of the Lambeth, Southwark and Lewisham Health Authority, with a population of 234 533. The total population is 72% white, 21% black (11% African Caribbean, 7.5% West African, and 2.5% black mixed), and 3% Asian, Bangladeshi, and Pakistani. The methodology has been described in detail elsewhere.<sup>12</sup>

Data were collected on patients' sociodemographic characteristics, including age, sex, ethnic group, social class, and place of residence. Face-to-face consultations with patients were conducted at 3 months and 1 year after stroke to collect data on functional ability and risk factors. Functional ability after stroke was measured with the Barthel Index. Data on physiological risk factors (atrial fibrillation, hypertension,<sup>13</sup> and diabetes) were collected at the time of stroke and after 3 months and 1 year. Diagnoses were based on patients' reported history and general practitioner and hospital records. A detailed description of the classification of physiological risk factors is presented elsewhere.<sup>5</sup>

Behavioral risk factor measures for alcohol consumption (units per week) and smoking status were based on standardized questions.<sup>14,15</sup> "Sensible" drinking limits were based on current published guidelines and defined as 14 U/wk for women and 21 U/wk for men,<sup>16-18</sup> where 1 unit is approximately equivalent to half a pint of beer, lager, or cider; a single measure of spirits; 1 glass of wine; or 1 small glass of fortified wine. Waist and hip circumferences were measured, and waist-to-hip ratio (WHR) was calculated. Obesity is defined as WHR >0.98 for men and >0.88 for women.<sup>19,20</sup> Change in smoking status is indicated by the patient giving up smoking or reducing the amount smoked compared with the amount smoked before the stroke. Measures of smoking status and alcohol use were taken at the time of stroke and at the 3-month and 1-year follow-ups. Obesity was measured at the time of stroke and 1-year follow-up only. Questions concerning obesity and reduction in the amount smoked were asked only of patients registered until July 1997.

Bivariate associations between patient characteristics and behavioral risk factors were analyzed with  $\chi^2$  tests. Multiple logistic regression was used to analyze associations between age, sex, ethnic group, social class, disability, physiological risks, and behavioral risk factors.

## Results

### Follow-Up Rates

Between January 1, 1995, and December 31, 1998, 1139 patients were registered with first-in-a-lifetime stroke. Of these, 377 (33.1%) died within the first 3 months after stroke, and of the survivors, 45 (5.9%) did not complete a 3-month follow-up questionnaire. Data at 1 year after stroke were available for all patients who registered before July 1997 (769). Of these, 311 died within the first year, and of the survivors, 36 (7.9%) were lost at 1-year follow-up. For the purposes of this study, 717 of 1139 patients are included for analysis at 3 months and 422 of 769 patients are included for analysis at 1 year after stroke.

### Characteristics of Stroke Patients

At the time of stroke, the average age of patients was 72 years. Just over half of the patients (593) were women. Most patients were white (905, 79.6%), but a relatively large minority were nonwhite, most of whom were black African or black Caribbean (181, 15.9%), with only 35 (3.1%) Asian, Bangladeshi, or Pakistani and 16 (1.4%) coming from other ethnic groups.

Three hundred fifty-eight patients (32.2%) were smokers at the time of stroke; 138 (13.2%) drank more than the weekly limit of alcohol; and 471 (56.3%) were obese.

### Prevalence of Behavioral Risk Factors After Stroke

At 3 months after stroke, 150 patients (22.2%) smoked, and 33 (4.9%) drank more than the weekly limit. At 1 year, the prevalence rates had changed very little: 89 (22.4%) were still smoking, and 15 (3.6%) were drinking excessively. One hundred thirty-two patients (36.1%) were still obese at 1 year. Table 1 shows the prevalence of behavioral risk factors at 3 months after stroke for smoking and alcohol use and at 1 year for obesity, identifying groups at high risk. Logistic regression analyses of associations between behavioral risk factors and sociodemographic and physiological risk factors are presented in Table 2.

Age, sex, and ethnicity were associated with behavioral risks in younger patients, with men and whites more likely to smoke at 3 months after stroke. Younger patients and whites were also more likely to be heavy drinkers at 3 months after stroke. Women and nonwhites were more likely to have a high WHR at 1 year. Patients still in hospital, nursing homes, or residential care at 3 months were also less likely to smoke, and none of these 149 patients were heavy drinkers. Fewer patients with physiological risk factors (atrial fibrillation, diabetes, and hypertension) reported being smokers, and the confidence intervals suggest that this association remained even after controlling for sociodemographic factors and stroke severity. There was no association between physiological risk factors and heavy drinking at 3 months or obesity at 1 year.

### Risk Factor Change

Of those at risk prior to their stroke, a large minority of smokers (82, 34.8%) reported giving up completely 3 months later. One hundred sixty-nine patients who smoked before their stroke were registered before July 1997; of these, 61 (36.1%) had given up completely and another 44 (26.0%) reported having reduced the amount smoked. Seventy-five (72.1%) of those who drank heavily before their stroke no longer drank more than the weekly limit.

Analysis of change within the first year suggests that for smoking and alcohol use, most patients who made lifestyle changes did so within the first 3 months after stroke. Of the 151 smokers before stroke who were still alive at 1 year, 62 (41.1%) gave up smoking, 53 of whom gave up within the first 3 months and only an additional 9 gave up between 3 months and 1 year. Seventy-three excessive alcohol users survived to 1 year, of whom 62 reduced their drinking to less than the weekly limits. Fifty-five of these did so within the first 3 months, and only 7 did so between 3 months and 1 year. Of those who were obese before stroke, 72 (41.1%) were no longer obese 1 year later.

A minority of patients without behavioral risk factors at the time of stroke had increased their risks factors afterward. Four patients who were not heavy drinkers before stroke drank more than the weekly limit 3 months later, and 30 patients (16.4%) who were not obese at the time of stroke were obese at 1 year. Data on smoking status after stroke

TABLE 1. Prevalence of Behavioral Risk Factors After Stroke

	Smoking (n=675)			Drinking More Than Weekly Limit (n=678)			High WHR* (n=364)		
	Total	n (%)	P	Total	n (%)	P	Total	n (%)	P
All patients	675	150 (22.2)		678	33 (4.9)		364	132 (36.3)	
Age, y									
<65	199	73 (36.7)	<0.001	205	18 (8.8)	<0.001	119	41 (34.5)	0.88
65–79	321	65 (20.3)		328	13 (4.0)		170	63 (37.1)	
80+	155	12 (7.7)		145	2 (1.4)		75	28 (37.3)	
Sex									
M	349	98 (28.1)	<0.001	356	24 (6.7)	<0.001	299	62 (31.2)	0.03
F	326	52 (16.0)		322	9 (2.8)		165	70 (42.4)	
Ethnicity									
White	518	131 (25.3)	<0.001	517	31 (6.0)	<0.001	282	95 (33.7)	0.06
Black or other	157	19 (12.1)		161	2 (1.2)		82	37 (45.1)	
Physical functioning†									
Independent	251	74 (29.5)	<0.001	257	23 (9.0)	<0.001	146	42 (28.8)	0.03
Moderate disability	301	63 (20.9)		294	8 (2.7)		177	70 (39.6)	
Severe disability	123	13 (10.6)		127	2 (1.6)		41	20 (48.8)	
Social class‡									
Manual	452	105 (20.6)	0.61	454	20 (4.4)	0.05	243	92 (32.1)	0.56
Nonmanual	199	41 (23.2)		196	13 (6.6)		106	34 (37.9)	
Not known	24	4 (16.7)		28	0 (0.0)		15	6 (40.0)	
Hospitalisation									
In hospital, nursing home, or residential care	145	13 (9.0)	<0.001	151	0 (0.0)	<0.001	63	29 (46.0)	0.08
Not in residential care	530	137 (25.9)		527	33 (6.3)		300	103 (34.3)	
Physiological risk factors									
Atrial fibrillation	98	11 (11.2)	0.01	96	3 (3.1)	0.07	58	25 (43.1)	0.24
No atrial fibrillation	577	139 (24.1)		582	30 (5.2)		306	107 (35.0)	
Diabetes	124	14 (11.3)	<0.001	123	4 (3.3)	0.48	57	22 (35.8)	0.69
No diabetes	551	136 (24.7)		555	29 (5.2)		307	110 (38.6)	
Hypertension	434	85 (19.6)	0.03	439	20 (4.6)	0.70	257	90 (35.0)	0.44
No hypertension	241	65 (27.0)		239	13 (5.4)		107	42 (39.3)	

\*Smoking and alcohol use were measured at 3 months after stroke; obesity, at 1 year.  
†Physical functioning was measured at 3 months and 1 year with the Barthel Index (BI). Physical functioning categories are defined as follows: independent, BI=20; moderate, BI 10–19; severe, BI <10.  
‡Social class was not known for 24 (3.6%). Of these, 19 described themselves as retired or permanently sick.

were available only for patients who were already smokers at the time of stroke. Factors associated with behavior change are presented in Table 3.

Giving up smoking at 3 months was associated with being nonwhite (black African, Caribbean, or other nonwhite ethnic group). Twenty patients (51.3%) from black ethnic groups did so compared with 62 (31.6%) of white patients. Living in institutionalized care was also associated with smoking cessation: 26 patients (66.7%) living in hospital, nursing home, or residential care had given up smoking compared with only 56 (28.4%) of those living in the community. All 16 patients living in hospital, nursing home, or residential care who previously drank more than the weekly limit had reduced their drinking at 3 months; therefore, place of residence could not be included in the logistic regression model for alcohol use.

**Discussion**

Previous work has discussed the appropriateness of physiological risk factor management after stroke,<sup>5</sup> but no research to date has focused on behavioral risk factors. This study investigated 2 key issues: the prevalence of behavioral risk factors after stroke and whether specific problem groups could be identified. We also aimed to identify characteristics about those who change risk factors after stroke to help understand what factors help or hinder risk factor change.

Younger patients, whites, men, and those living in the community (as opposed to residential hospital or nursing home care) were more likely to be smokers, and these groups could be targeted with interventions to promote smoking cessation tailored to meet their needs. Younger patients and whites were also more likely to be at risk from excessive



**TABLE 2. Association Between Behavioral Risk Factors and Sociodemographics, Physical Functioning, and Physiological Risk Factors After Stroke**

	Smoking			Drinking More Than Weekly Limit			High WHR*		
	OR	95% CI	P	OR	95% CI	P	OR	95% CI	P
Age, y									
<65	1		<0.001	1		0.02	1		0.71
65–79	0.40	0.26–0.63		0.42	0.19–0.93		1.16	0.69–1.95	
80+	0.13	0.06–0.27		0.17	0.04–0.84		0.93	0.47–1.82	
Women	0.65	0.43–0.99	0.05	0.59	0.26–1.35	0.21	1.67	1.06–2.63	0.03
Nonwhite ethnicity	0.28	0.16–0.50	<0.001	0.17	0.04–0.73	0.02	1.70	0.98–2.96	0.06
Physical functioning†									
Independent	1		0.81	1		0.19	1		0.31
Moderate disability	1.15	0.74–1.79		0.50	0.21–1.18		1.34	0.82–2.18	
Severe disability	1.00	0.42–2.40		1.44	0.29–7.18		1.85	0.77–4.42	
Social class‡									
Manual	1		0.82	1		0.19	1		0.51
Nonmanual	1.15	0.73–1.80		0.60	0.28–1.29		1.29	0.78–2.13	
Not known	1.15	0.34–3.92		...	...		1.62	0.54–4.91	
Living in residential care, hospital, or nursing home	0.38	0.17–0.84	0.02	...	...	...	1.15	0.59–2.28	0.68
Physiological risk factors									
Atrial fibrillation	0.54	0.27–1.08	0.08	1.03	0.29–3.71	0.96	1.33	0.73–2.41	0.35
Diabetes	0.46	0.24–0.88	0.02	0.90	0.29–2.81	0.85	0.91	0.49–1.72	0.78
Hypertension	0.70	0.46–1.05	0.08	0.94	0.44–2.01	0.88	0.80	0.49–1.29	0.36

OR indicates odds ratio.  
\*Smoking and alcohol use were measured at 3 months after stroke, obesity, at 1 year.  
†Physical functioning was measured at 3 months and 1 year with the Barthel Index (BI). Physical functioning categories are defined as follows: independent, BI=20; moderate, BI 10–19; severe, BI <10.  
‡Social class was not known for 24 (3.6%). Of these, 19 described themselves as retired or permanently sick.

drinking; nonwhites and women were more likely to be obese. These groups could also be targeted with appropriate interventions to reduce their risk of second stroke.

A large minority of those with risk factors did modify their lifestyles after stroke; in particular, most excessive drinkers reduced their alcohol consumption within the first year. However, despite some successes, not all patients managed to change their risk factors. Half of those who still smoked at 3 months had reduced the amount they smoked, suggesting that they were willing to change their risk factors but might have needed further support to give up completely. A minority continued to drink more than the weekly limit, and most obese patients did not reduce their WHR.

Apart from living in institutionalized care (hospitals, nursing homes, or residential care), there were no particular patient characteristics associated with behavioral change, although nonwhites were more likely to give up smoking. Older patients were no less likely than their younger counterparts to change any behavioral risk factors after stroke, and this finding supports previous research<sup>10</sup> emphasizing that older people should not be excluded from secondary prevention care because they are equally willing to change.

Of those who stopped smoking or cut down on alcohol use, most did so in the first 3 months, suggesting that smoking and

alcohol use might be more amenable to change during this time. An alternative interpretation might be that health professionals offer secondary prevention advice only in the first 3 months, failing to deliver appropriate information in the longer term. However, further investigation is needed to determine whether this is the case.

These findings are based on a limited number of questions about patient characteristics and behavioral risk factors and as such can provide only an outline of the relationships between them. If the problems of inadequate management of behavioral risk factors are to be addressed, more research is needed into the actual process of change to find out why some patients change their risk factors while others do not. Trials of interventions to promote behavior change have shown positive results,<sup>9,10</sup> but we do not know whether these interventions work for patients with stroke. Little is known about current health service management of behavioral risk factors, what secondary prevention interventions are used in practice, and which patients are being targeted.

We are currently conducting further research to gain a better understanding of risk factor management and the process of change, including interviews with stroke patients about their experiences of risk factor change and observational work to explore the role of health services in promoting secondary prevention or stroke.



TABLE 3. Association Between Change in Behavioral Risk and Sociodemographics, Physical Functioning, Physiological Risk Factors, and Health Service Use After Stroke

	Give up smoking			Reduce Drinking to Less Than Weekly Limit			Reduce to Nonobese*		
	OR	95% CI	P	OR	95% CI	P	OR	95% CI	P
Age, y									
<65	1		0.84	1		0.63	1		0.62
65–79	1.09	0.57–2.07		1.02	0.36–2.91		0.66	0.25–1.77	
80+	0.78	0.21–2.86		2.87	0.28–29.62		1.00	0.26–3.82	
Women	1.24	0.64–2.40	0.32	0.48	0.13–1.84	0.29	0.72	0.29–1.76	0.27
Nonwhite ethnicity	2.21	1.01–4.82	0.03	1.73	0.32–9.43	0.53	0.53	0.18–1.62	0.73
Physical functioning†									
Independent	1		0.19	1		0.12	1		0.93
Moderate/mild disability	1.11	0.56–2.21		3.17	0.98–10.30		0.90	0.35–2.28	
Severe disability	2.01	0.65–6.18		0.82	0.10–7.02		0.74	0.14–3.80	
Social class‡									
Manual	1		0.23	1		0.51	1		0.08
Nonmanual	2.09	0.90–5.57		1.42	0.50–4.08		0.41	0.14–1.67	
Not known	2.18	0.42–11.44		...	...		...	...	
Living in residential care, hospital, or nursing home	3.16	1.20–8.35	0.02	...	...	...	0.45	0.12–1.67	0.23
Physiological risk factors									
Atrial fibrillation	1.69	0.62–4.59	0.31	0.86	0.12–6.18	0.89	0.56	0.20–1.63	0.29
Diabetes	1.22	0.48–3.09	0.67	1.28	0.29–5.70	0.74	3.13	0.59–16.66	0.18
Hypertension	1.61	0.87–2.97	0.13	0.69	0.24–1.95	0.48	2.09	0.89–4.89	0.09

OR indicates odds ratio.  
\*Smoking and alcohol use were measured at 3 months after stroke; obesity, at 1 year.  
†Physical functioning was measured at 3 months and 1 year with the Barthel Index (BI). Physical functioning categories are defined as follows: independent, BI=20; moderate, BI 10–19; severe, BI <10.  
‡Social class was not known for 24 (3.6%). Of these, 19 described themselves as retired or permanently sick.

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# Health care follow-up after stroke: opportunities for secondary prevention

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Redfern J, McKevitt C, Rudd AG and Wolfe CDA. Health care follow-up after stroke: opportunities for secondary prevention. *Family Practice* 2002; **19**: 378–382.

**Background.** Stroke patients have a 15-fold increased risk of a recurrence, but management of risk factors following stroke has been found to be unsatisfactory. Little is known about health service follow-up of patients after stroke or, consequently, the opportunities for providing secondary prevention to patients.

**Objective.** The aim of the present study was to investigate the relationship between health service follow-up and management of risk factors after stroke.

**Methods.** The study used data from the population-based South London Stroke Register, collected prospectively between 1995 and 1998. Main measures included risk factor change and follow-up by hospital physicians, GPs and district nurses. Logistic regression was used to determine relationships between these measures.

**Results.** Seven hundred and seventeen stroke survivors were registered with first stroke between 1995 and 1998. Most patients were followed-up on at least one occasion by at least one service within the first 3 months after stroke: 51% saw a hospital specialist; 72% saw a GP; and 14% saw a community nurse. However, 14% of patients did not see a doctor at all. Disabled patients were less likely to see a doctor, only 17% of severely disabled patients seeing a hospital specialist [odds ratio (OR) 0.17; 95% confidence interval (CI) 0.07–0.41]. Doctor-led follow-up was related to treatment of physiological risk factors (e.g. 73% of hypertensive patients who had seen a GP were treated compared with 59% who had seen only a hospital specialist and 47% who had seen neither). Contact with health services was not associated with behavioural risk factor change.

**Conclusions.** Opportunities for delivering secondary prevention existed through a range of services, but problems of continuity and effectiveness of care are evident. Further investigation is needed to determine how best to intervene to address these issues. In other words, whether interventions should concentrate on improving access and availability of current services, or whether the focus should be on making current strategies more effective.

**Keywords.** Prevention, risk factors, stroke.

## Introduction

Stroke survivors, who have a 15-fold increased risk of further vascular events compared with the general population,<sup>1</sup> are an important group to target if mortality rates are to be reduced.

Secondary prevention requires appropriate management of risk factors, but our previous research indicates that risk factor management in the stroke population is poor (e.g. 30% of patients with hypertension were not treated 3 months after stroke).<sup>2,3</sup> In this paper, we now investigate health service opportunities for secondary prevention.

In the UK, as in many other areas of Europe, opportunities for secondary prevention arise through a range of services. These include follow-up by a specialist physician in hospital out-patient clinics, or by a primary care doctor (GP) in a community surgery or in the patient's own home. Other primary care professionals who may provide secondary prevention include the 'practice nurse' (whose other duties include providing chronic disease management in partnership with the GP), or a

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community-based 'district nurse' (whose main responsibilities include nursing care, health promotion and preventive activities).<sup>4</sup>

Research on primary prevention identified failures of follow-up, advice and monitoring as avoidable contributory factors to death from stroke and hypertension.<sup>5</sup> Evidence-based guidelines for the delivery of secondary prevention have been produced,<sup>6-8</sup> but little is known about current practice. This paper focuses on the following questions: what factors influence patient contact with health professionals? Is contact associated with risk factor management?

## Methods

The study used data from the population-based South London Stroke Register, which, since 1995 prospectively collects data on first ever strokes in patients of all age groups. Twelve overlapping referral sources are used to attain complete notification in the study area comprising 22 wards of the Lambeth, Southwark and Lewisham Health Authority (LSLHA), with a population of 234 533. The methodology has been described in detail elsewhere.<sup>9</sup>

Data were collected on patients' socio-demographic characteristics and risk factors at the time of stroke. Patients were seen by a trained interviewer 3 months after stroke and data collected on: place of residence and functional ability (Barthel Index); physiological risk factors (hypertension, atrial fibrillation, diabetes and coronary heart disease); and behavioural risk factors (smoking, heavy drinking and obesity). Risk factor management 3 months after stroke was defined as treatment with anticoagulant, antiplatelet or antihypertensive medication, smoking cessation and reduction in drinking. Detailed descriptions of patients' risk factors are presented elsewhere.<sup>2,3</sup> Data on health service follow-up within 3 months after stroke included: one or more visits to a hospital out-patient clinic or GP surgery, or a home visit from a GP or district nurse.

Data were analysed using chi-square tests and multiple logistic regression.

## Results

Between 1 January 1995 and 31 December 1998, 1139 patients were registered with first stroke. Of these, 377 (33.1%) died within the first 3 months after stroke and, of the survivors, 45 (5.9%) did not complete a 3-month follow-up questionnaire. Data from 717/1139 patients are therefore analysed.

Patient characteristics are presented in Table 1. Most patients (558, 87.5%) had at least one modifiable risk factor at the time of stroke, and 280 (43.9%) had at least two.

Of those not living in hospital, 317 (55.1%) saw a specialist in an out-patient clinic within the first 3 months

TABLE 1 Characteristics of patients (n = 717)

	n (%)
Age of patients surviving to 3 months (mean no. of years)	69.5
Sex	
Male	377 (52.6)
Female	340 (47.4)
Self-defined ethnicity	
White	547 (76.4)
Black Caribbean	98 (13.7)
Black African or other	37 (5.2)
Social class (occupation)	
Manual (III manual, IV, V)	475 (66.3)
Non-manual (I, II, III non-manual)	210 (29.3)
Social class not known*	32 (4.5)
Place of residence	
Living at home	553 (77.5)
In hospital	101 (14.1)
In a nursing home	47 (6.6)
In residential care	13 (1.8)
Functional ability	
Independent (BI = 20)	263 (37.15)
Moderate disability (BI = 10 < 20)	311 (43.9)
Severe disability (BI < 10)	134 (18.9)

Missing data: ethnicity, one patient; place of residence, two patients; Barthel Index (BI), nine patients.

\* Of those whose social class was not known, 24 were retired.

after stroke. Care of the elderly specialists were visited most commonly (121, 21.0%), followed by general physicians (56, 9.7%), rehabilitation specialists (44, 7.7%), neurologists (38, 6.6%) and others (55, 9.6%).

Two hundred and sixty-seven patients (44.7%) visited a GP surgery and a further 165 (27.6%) were visited by a GP at home. Patients not initially admitted were more likely to have seen a GP (111, 80.4%) compared with only 328 (70.2%) of those previously hospitalized ( $P = 0.02$ ). Figure 1 illustrates the overlap between hospital and

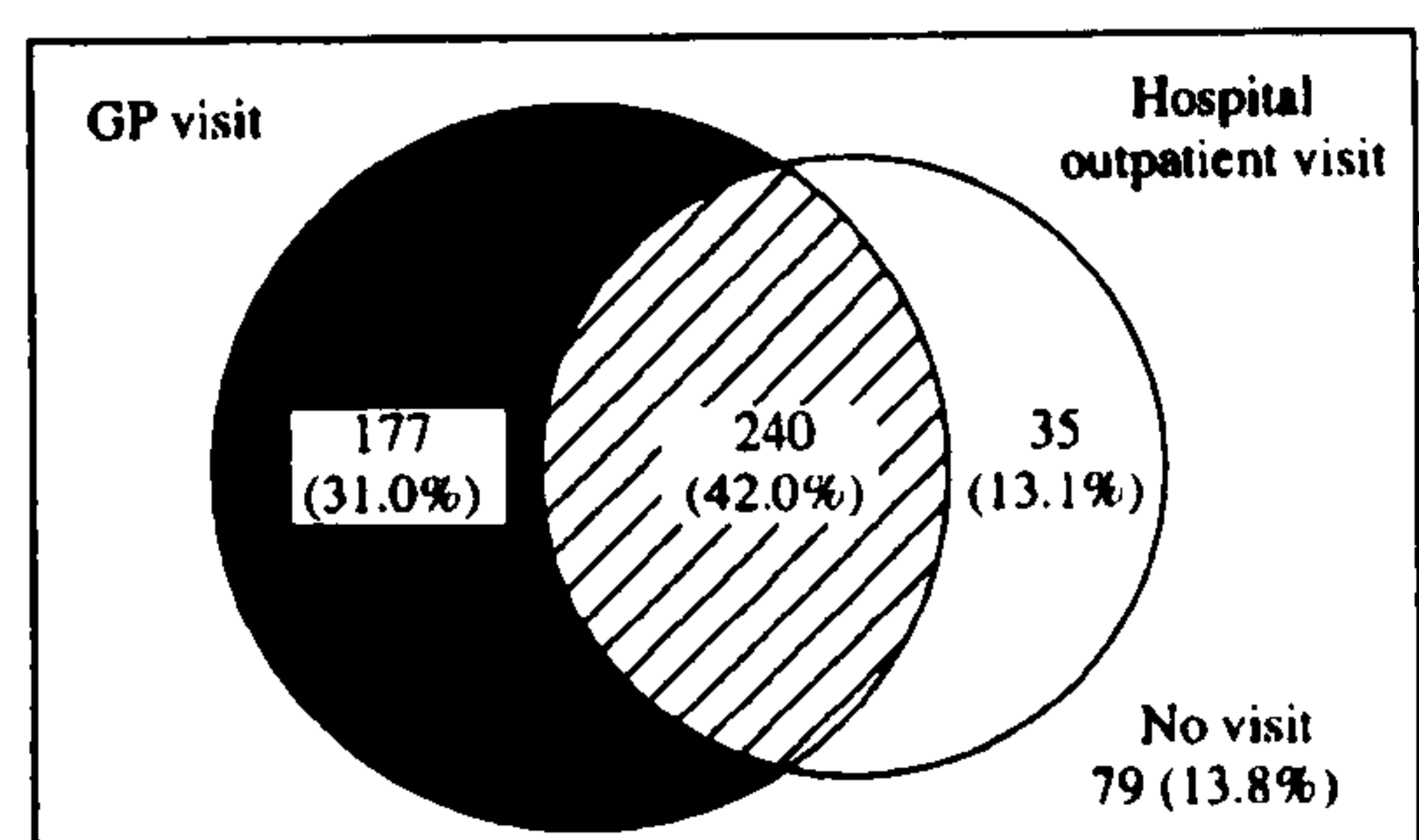


FIGURE 1 Proportion of patients followed-up by GPs and hospital specialists in the first 3 months after stroke. Based on 571/605 patients who answered both questions. Twenty-six patients did not answer the question on out-patient attendance (15 had seen a GP, 11 had not), four patients did not answer the question on GP visits (two had seen a specialist, two had not)



general practice follow-up. Of those who had no contact with any doctor after leaving hospital, 68 (90.7%) had at least one modifiable risk factor and 26 (34.7%) had at least two. Only patients living at home were eligible for district nurse support. Of these, 85 (14.2%) had seen a district nurse within the first 3 months.

Associations between follow-up and patient characteristics are presented in Table 2. Table 3 illustrates relationships between follow-up, patient characteristics and additional risk factors adjusting for all other factors.

Disabled patients were less likely to have consulted a doctor in any setting (out-patients, GP surgery or at home), but just under two-thirds of severely disabled patients had been visited by a district nurse. Age was also related to GP care, those aged over 65 being less likely to be followed-up and, although elderly patients were more likely to have received support from district nurses, only a quarter of those aged 80 years or more had done so. Those living in nursing homes or residential care rarely attended out-patients although they were equally likely to have seen a GP (all but one receiving a domiciliary visit

from the doctor). After adjusting for age and disability, no associations were found between follow-up and gender, ethnicity or social class.

There was no obvious relationship between having additional risk factors at the time of stroke and contact with health professionals. Patients with a diagnosis of diabetes or hypertension were more likely to have been visited by a district nurse, but no other associations were statistically significant.

Ischaemic stroke patients who had seen either a specialist or a GP were more likely to be prescribed medication (Table 4); however, having contact with both did not improve the likelihood of treatment.

No association was found between follow-up and smoking cessation or reduction of heavy drinking.

Discussion

This is the first study investigating opportunities for secondary prevention in the stroke population. Since

TABLE 2 Associations between patient characteristics and health care follow-up in the first 3 months after stroke

	Visit out-patients' clinic <sup>a</sup>			Visit or receive visit from GP <sup>a</sup>			Have district nurse support <sup>b</sup>		
	Total patients	n (%)	P-value	Total patients	n (%)	P-value	Total patients	n (%)	P-value
Total	575	317 (55.1)		597	391 (72.5)		556	85 (15.3)	
Age									
<65 years	177	120 (67.8)	<0.001	181	150 (82.9)	0.001	178	14 (7.9)	<0.001
65–79 years	269	145 (53.9)		280	189 (67.5)		266	43 (16.2)	
≥80 years	129	52 (40.3)		136	93 (68.3)		112	28 (25.2)	
Gender									
Male	303	172 (56.8)	0.41	314	244 (77.7)	0.002	300	35 (11.7)	0.01
Female	272	145 (53.3)		283	188 (66.4)		256	50 (19.5)	
Ethnicity									
White	449	246 (54.8)	0.74	462	330 (71.4)	0.58	462	55 (12.9)	0.005
Black Caribbean	71	42 (59.2)		77	57 (74.0)		72	20 (27.8)	
Black African or other	55	29 (52.7)		58	45 (77.6)		58	10 (17.2)	
Physical functioning									
Independent (BI = 20)	252	169 (67.1)	<0.001	257	208 (80.9)	<0.001	258	11 (4.3)	<0.001
Moderate disability (BI = 10 < 20)	253	136 (53.8)		265	173 (65.2)		260	51 (19.6)	
Severe disability (BI < 10)	70	12 (17.1)		75	51 (68.0)		38	23 (60.5)	
Social class									
Manual (III manual, IV, V)	392	215 (54.9)	0.44	406	295 (72.7)	0.90	382	64 (16.8)	0.14
Non manual (I, II, III non-manual)	164	94 (57.3)		169	122 (72.2)		157	17 (10.8)	
Retired, class n/k	19	8 (42.1)		22	15 (68.2)		17	4 (23.5)	
Place of residence									
Nursing home or residential care	55	7 (12.7)	<0.001	58	41 (70.7)	0.76	545	84 (15.4)	0.56
At home	520	310 (59.6)		539	391 (72.5)		11	1 (9.1)	

Chi-square tests comparing follow-up between different patient groups (unadjusted).  
Missing data: Barthel Index (BI), nine patients; socio-demographic characteristics, four patients; out-patient attendance, 29 patients; GP contact, seven patients; district nurse support, two patients.  
<sup>a</sup> Based on patients discharged from hospital 3 months post-stroke.  
<sup>b</sup> Based on patients discharged from hospital and not living in nursing homes 3 months post-stroke.

TABLE 3 Health service follow-up adjusting for patient characteristics and risk factors within first 3 months after stroke

	Visit out-patients' clinic <sup>a</sup>			Visit GP or receive visit from GP <sup>a</sup>			Have district nurse support <sup>b</sup>		
	OR	95% CI	P-value	OR	95% CI	P-value	OR	95% CI	P-value
Age									
<65 years	1		0.10	1		0.04	1		0.03
65–79 years	0.62	(0.39, 1.00)		0.52	(0.30, 0.88)		2.13	(0.96, 4.75)	
≥80 years	0.55	(0.29, 1.02)		0.70	(0.36, 1.38)		3.54	(1.38, 9.07)	
Female	1.27	(0.83, 1.95)	0.27	0.75	(0.48, 1.17)	0.20	1.33	(0.71, 2.51)	0.37
White	1		0.66	1		0.86	1		0.19
Black Caribbean	0.91	(0.49, 1.71)		0.98	(0.52, 1.87)		2.18	(0.96, 4.98)	
Black African or other	0.72	(0.36, 1.45)		1.23	(0.56, 2.67)		1.21	(0.43, 3.45)	
Physical functioning <sup>c</sup>									
Independent (BI = 20)	1		<0.001	1		0.01	1		<0.001
Moderate disability (BI = 10 < 20)	0.62	(0.41, 0.94)		0.50	(0.32, 0.79)		3.55	(1.70, 7.42)	
Severe disability (BI < 10)	0.17	(0.07, 0.41)		0.53	(0.25, 1.13)		26.78	(9.58, 74.86)	
Social class									
Non-manual (I, II, III non-manual)	1		0.67	1		0.85	1		0.08
Manual (III manual, IV, V)	0.84	(0.54, 1.29)		0.88	(0.56, 1.38)		2.00	(0.96, 4.20)	
Retired, class n/k	1.11	(0.32, 3.90)		0.93	(0.29, 2.95)		3.93	(0.80, 19.37)	
Living in nursing home or residential care	0.19	(0.07, 0.55)	0.002	1.09	(0.51, 2.35)	0.83	0.11	(0.01, 1.56)	0.11
Behavioural risk factors									
Smokers	0.98	(0.63, 1.54)	0.95	0.99	(0.62, 1.59)	0.98	1.18	(0.60, 2.35)	0.63
Alcohol use									
Non-drinker	1		0.13	1		0.14	1		0.49
Moderate drinker	1.54	(0.98, 2.42)		1.58	(1.01, 2.47)		0.81	(0.43, 1.51)	
Heavy drinker <sup>d</sup>	1.74	(0.89, 3.44)		1.30	(0.64, 2.64)		1.36	(0.51, 3.64)	
High waist–hip ratio	0.67	(0.45, 1.01)	0.06	0.89	(0.58, 1.35)	0.57	1.11	(0.60, 2.07)	0.73
Clinical risk factors:									
Atrial fibrillation	1.43	(0.78, 2.64)	0.25	1.84	(0.97, 3.52)	0.40	1.08	(0.48, 2.45)	0.85
Diabetes	1.39	(0.80, 2.42)	0.24	1.32	(0.74, 2.34)	0.58	2.93	(1.47, 5.84)	<0.01
Hypertension	0.97	(0.66, 1.43)	0.87	0.90	(0.60, 1.36)	0.98	1.89	(1.02, 3.50)	0.05
Coronary heart disease	0.74	(0.47, 1.14)	0.17	0.80	(0.51, 1.25)	0.83	1.11	(0.59, 2.09)	0.75

Odds ratios (ORs) adjusted for all other factors.  
<sup>a</sup> Based on patients discharged from hospital 3 months post-stroke.  
<sup>b</sup> Based on patients discharged from hospital and not living in nursing homes 3 months post-stroke.  
<sup>c</sup> BI = Barthel Index.  
<sup>d</sup> Heavy drinking defined as >14 units a week for women; >21 units a week for men (where 1 unit = half pint of beer, one small glass of wine or spirits).

most patients had at least one contact with health services in the first 3 months after stroke, there were opportunities for providing secondary prevention. However, 14% did not see any doctor, a quarter did not see a GP and ~10% of those who attended out-patient clinics did not see a stroke-related specialist. Because data were not collected on the reason for patients' contact with professionals, we cannot assume that appropriate secondary prevention was provided to those who were followed-up.

Patients with disabilities were less likely to be followed-up by any doctor. Older patients were less likely to see a GP. These apparent inequalities in service provision require explanation.

Health professionals are encouraged to target those most at risk,<sup>6–8</sup> but in this study patients with additional risk factors were no more likely to be followed-up.

Follow-up was not associated with behavioural risk factor change. This is difficult to interpret, but may reflect difficulties in changing behaviours (e.g. quitting smoking). Alternatively, health professionals may choose not to prioritize behavioural risk factors. GPs may be less interested in health promotion or behavioural change,<sup>10</sup> finding it difficult to discuss lifestyle issues with patients.<sup>11</sup>

Since all patients are at risk after stroke, all patients require secondary prevention. Patients with disabilities, the elderly and those living in residential homes may need

TABLE 4 Associations between risk factor management and health care follow-up

	Followed-up by hospital specialist or GP within 3 months		No contact		P-value
	Total patients	n (%)	Total patients	n (%)	
Treated with antihypertensives	315	224 (71.1)	54	26 (48.2)	0.001
Treated with anticoagulants	40	14 (35.0)	10	1 (–)	0.246 <sup>a</sup>
Treated with antiplatelets	322	273 (84.8)	59	42 (71.2)	0.011
Given up smoking	179	54 (30.2)	25	10 (40.0)	0.321
Reduced heavy drinking <sup>b</sup>	82	56 (68.3)	6	3 (–)	0.391 <sup>a</sup>

Chi-square tests comparing those followed-up versus those having no contact with professionals.  
<sup>a</sup> Small numbers; data should be interpreted with caution.  
<sup>b</sup> Heavy drinking defined as >14 units a week for women; >21 units a week for men (where 1 unit = half pint of beer, one small glass of wine or spirits).

specific targeting to ensure equitable access to those who can prescribe and monitor their treatment. However, attending services does not in itself constitute risk factor management. Further work is needed to establish what is provided during follow-up and identify facilitators of and barriers to secondary prevention provision.

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## **Appendix 2. Topic guide for patient interviews (intervention development)**

*General understanding of stroke and experiences of prevention*

### **The stroke experience**

Tell me a bit about your stroke [prompt: what happened to the patient]

Affect of stroke on patients' life – changes since the stroke

People who have been important to patient since the stroke [prompt: health professionals, family, friends]

### **Monitoring**

Hospital outpatient visits [prompt reason for attendance]

GP visits [prompt reason for attendance, frequency]

Follow up about stroke [prompt frequency, what happened/happens at visit]

### **Understanding of stroke in general**

Why patient had the stroke

Things that can cause strokes in general

What type of stroke patient had [prompt: haemorrhage, ischaemic]

Definition of what their type of stroke is

### **Future health**

Things patient worries about these days

Worries about health [prompt future health]

Worries about stroke [prompt future stroke]

Chances of patient having another stroke [prompt how much of a risk, why patient perceives they are at risk/not at risk]

Things that can be done to prevent strokes [prompt: things to prevent the patient having another stroke]

### **Information and education**

How patient has learnt about stroke and prevention of stroke

Information received about stroke and prevention [prompt written or verbal; who from, when received, quality of information]

Anything patient would have liked to know about the stroke or stroke prevention that hasn't been explained.

## *Medication general*

### **Medication**

Current medication taken

Current medication for stroke [prompt aspirin]

Length of time taken [prompt pre stroke/post stroke]

The name of the medication [if don't know prompt for the type of medication group]

What the medication is for

Previously prescribed medication [prompt changes to medication]

Decisions about treatment

### **Current medication taking**

How/When the patient takes the medication

Concordance with medication [prompt frequency, prompt stopping medication]

Problems with the medication [prompt side effects]

Barriers/Difficulties taking medication [prompt remembering, problems getting a prescription]

Monitoring of medication [prompt repeat prescription, whether see doctor or practice nurse]

Written information about medications [prompt content, quality]

### **Understanding of medications**

How the medication works

Whether the patient can tell the medication is working

Feelings about taking the medication

Whether the medication will stop the patient having another stroke

## *Risk factors clinical*

### **Blood pressure**

Whether patient knows their blood pressure [prompt who told patient]

What a normal blood pressure is [prompt who told patient]

Whether patient has high blood pressure [prompt how know blood pressure is high/OK]

Definition of what high blood pressure is

What having high blood pressure means to the patient

Last blood pressure check

Current medication for blood pressure

Prior medication for blood pressure

What you eat and blood pressure

Advice about blood pressure

Written information about blood pressure

Looking after blood pressure and stroke prevention

### **Cholesterol**

What patient's cholesterol is [prompt who told patient]

What a normal cholesterol is [prompt who told patient]

Whether patient has high cholesterol



Definition of what cholesterol/high cholesterol is  
What having high cholesterol means to the patient  
Whether cholesterol was related to the patient's stroke  
Last cholesterol check  
Medication for cholesterol  
Medication for cholesterol prior to stroke  
What you eat and cholesterol  
Advice about cholesterol  
Written information about cholesterol  
Looking after cholesterol and stroke prevention

### **Atrial Fibrillation**

Whether patient has any heart problems [prompt whether patient has atrial fibrillation, how the patient knows, tests the patient has had]  
Definition of what atrial fibrillation is  
What having atrial fibrillation means to the patient  
Whether atrial fibrillation was related to the patient's stroke  
Medication for atrial fibrillation [prompt: how long been taking, how medication works]  
Prior medication for atrial fibrillation  
Monitoring of medication [check postal patient]  
Advice about anticoagulants and antiplatelets  
Written information about anticoagulants and antiplatelets  
Looking after atrial fibrillation and stroke prevention

### **Diabetes**

Whether patient has diabetes  
Definition of what diabetes is  
Last recorded HbA1c  
What a normal HbA1c is  
What having diabetes means to the patient [in terms of changes to their lives, monitoring, medication etc.]  
Whether diabetes was related to the patient's stroke  
Monitoring of diabetes  
Medication for diabetes  
What you eat and diabetes  
Looking after diabetes and stroke prevention

### *Lifestyle*

#### **Smoking**

Whether patient smokes  
Whether smoking is a perceived health problem [prompt for whether smoking anything is a health problem, amount that is OK]  
Whether smoking was related to the patient's stroke  
Attempts to quit smoking/cut down [prompt whether since stroke, what happened, strategies for giving up]  
Reasons for giving up  
Barriers to giving up [prompt generally, and from experience]  
Health professional advice to give up [prompt, who, when, content and quality of advice]



Written information about smoking [prompt, who provided, when, content and quality of advice]  
Smoking support [medications (patches, gum), smoking clinics]  
Giving up and stroke prevention

## **Alcohol**

Whether patient drinks alcohol  
Whether drinking alcohol is healthy/a health problem [prompt for how much alcohol is healthy]  
Whether drinking alcohol was related to the patient's stroke  
Attempts to change alcohol use [prompt whether happened since the stroke, what happened, strategies for changing drinking patterns]  
Reasons for changing drinking patterns  
Barriers to changing drinking patterns  
Health professional advice to cut down/give up [prompt, who, when]  
Information about alcohol use [prompt written, verbal, who provided, quality of information]  
Alcohol use support [drinking clinics]  
Alcohol and stroke prevention

## **Diet**

Whether what you eat is important for being healthy  
What eating 'healthy food' means to the patient [prompt for good, bad foods]  
Whether patient eats healthy food  
Whether patient's diet was related to their stroke  
Types of food that are bad for you after a stroke [prompt: salt, high cholesterol foods, sweet foods if diabetic]  
Changes to diet since the stroke [prompt: what changes, what happened, strategies for changing diet]  
Reasons for changing diet  
Barriers to changing diet  
Health professional advice to change patient's diet [prompt, who, when]  
Written information about diet [prompt who provided, when, quality of information]  
Dietary support [nutritionist, dietician]  
Diet and stroke prevention

## **Obesity**

Weight  
What overweight means?  
Attempts to lose weight [prompt what happened, strategies for giving up]  
Attempts to lose weight since the stroke [prompt what happened, strategies for giving up]  
Reasons for losing weight/trying to lose weight  
Barriers to losing weight  
Health professional advice to lose weight [prompt, who, when]  
Written information about losing weight [prompt who provided, when, quality of information]  
Support [nutritionist, dietician etc]  
Beliefs about weight/obesity and stroke prevention

## **Exercise**

Whether exercise is important for being healthy

Amount of exercise patient does [prompt for examples of exercise]

What 'exercise' means [prompt for type of exercise]

Whether exercise had anything to do with their stroke

Attempts to change exercise pattern since the stroke[prompt what happened, strategies for giving up]

Reasons for trying to changing exercise

Barriers to exercising

Health professional advice about exercise [prompt who, when]

Written information about exercise [prompt who provided, when, quality of information]

Exercise support [e.g. health centres specialising in exercise for those with disabilities]

Exercise and stroke prevention

Appendix 3. Observation Schedule (intervention development)

Clinic date:	<div></div> <div></div> <div></div>	Hospital:	[Hospital A]/[Hospital B]		
Doctor					
Serial no:	<div></div> <div></div> <div></div>	Time start:	<div></div>	Time stop:	<div></div>
Age:	<div></div>	DOB:	<div></div> <div></div> <div></div>		
Sex:	male / female		Ethnicity:		
Date of stroke:	<div></div> <div></div> <div></div>				
Time since last episode:	<div></div>	weeks	<div></div>	months	<div></div> years
Type of patient:	New / follow-up				
Mobility:	Walking / walk with stick / wheelchair				
Communication:	No problem / problems / interpreter				
Carers:	No carer / partner / relative / friend / formal / other / dk				
Type of stroke:	Ischaemic / haemorrhage / TIA / suspected stroke / not stroke				
Behavioural risk factors:	Smoker / drinker / obesity				
Clinical risk factors:	Hypertension / AF / diabetes / cholesterol				
Medication:	Aspirin / antiplatelet / anticoagulant Antihypertensives / cholesterol lowering / diabetes treatment				
Blood pressure:	<div></div> <div></div>	Fine/ too high / other / not specified			
Outcome:	Discharged / follow-up / referred elsewhere				
Secondary prevention recurrence explicit:	yes / no				
Risk size:	% given / other / no risk size				
No. questions asked by doctor:			No. questions asked by patient:		
<div></div>			<div></div>		



## **Appendix 4. Topic guide for trial staff interviews**

### *Staff experiences of working on the trial*

**Can you describe your experience of working on Stop Stroke over the past year?**

prompt what has been easy, difficult, challenging, enjoyable

**What have been the biggest challenges for you?**

How have you managed to overcome these challenges?

Any unresolved issues/problems that you would like to discuss?

Who they go to if you have problems or issues you wish to raise?

**Specific challenge questions:**

There have been a number of staff changes in the past year, How has this affected the trial?

[Prompt each SLSR1, FUP1 Admin1 leaving, FUP2 SLSR3 starting].

The neuro-vascular clinic was set up in the last year. I know there have been some problems with SLSR recruitment from this clinic – can you describe what are the main problems?

How have the challenges affected SLSR recruitment/ the trial and intervention delivery

### *Roles and responsibilities*

**You are the [trial coordinator/research assistant], what are the main tasks that you do?**

What are the easiest tasks?

What are the most difficult tasks?

How have your main tasks changed over the past year?

Are there any other people involved in the Stop Stroke process and what tasks do they do?

**Specific role questions:**

Annual leave - what happens to the intervention if members of staff go on leave.

Staff absence and workload - SLSR3 being too busy to do aspects of SLSR work – how has this affected the trial?

### *Satisfaction*

**Are you happy with the way the trial is running?**

Things which could be improved

What is needed to improve these things

### *The intervention/trial*

**Can you describe the intervention to me?**

What exactly are the components of the intervention?

Who gets the intervention?

Are there any people who are not eligible for the intervention?

**Have there been any changes to the intervention over the past year –**  
Changes to content of the intervention?  
Changes to who gets the intervention?  
Other changes influencing the intervention process?

**What do you understand by the term ‘pragmatic trial’?**  
Reassure: It is OK if you don’t understand the term.

*Communication*

**You were asked to keep diaries during the first year – how difficult was this?**

Did the diaries help you to identify problems?  
Did the diaries help resolve any problems?

**We have started having weekly meetings about the trial do you find these meetings helpful?**

Did you have meetings throughout the past year?  
If no – what did you have instead?

*Specific questions to clarify individual tasks*

*For Research Assistant:*

**Blood test data collection.**

Prompts:

What the blood tests are for?

Delays in taking bloods? If yes – when did this start, how was it? If no – when do you think the blood tests will start?

How will the blood testing process happen?

What were the main reasons for the delay in taking bloods?

Training in phlebotomy

Confidence in taking bloods

**Support**

In the last Stop Stroke meeting you mentioned that you did not feel supported in your tasks, is there anything you want to say about this?

*For Trial Coordinator:*

**Trial administration**

Intervention delivery

Patient monitoring (prompt databases, paper recording)

SLSR processes

Appendix 5. Stop Stroke Team Weekly Diary

Name:

Date:

Recruitment Issues <i>List any problems and what you did to try to resolve them</i>
Data collection problems <i>List any problems and what you did to try to resolve them</i>
Trial process issues <i>List any problems and what you did to try to resolve them</i>
Programme failures <i>List any problems and what you did to try to resolve them</i>
Other issues <i>List any problems and what you did to try to resolve them</i>



## **Appendix 6. Topic guide for patient interviews (intervention evaluation)**

### *Patients' experiences of secondary prevention*

**Can you tell me a bit about what has happened to you since the stroke?**  
Prompts:

#### **Hospital visits**

Whether patient has been (back) to the hospital since your stroke?

If yes, what happened, who saw, purpose of appointment, advice given, treatments, did they do any tests]

If no, reasons why not – have any appointments been booked, missed]

#### **GP care**

Whether patient has seen their GP since your stroke?

If yes, what for, how many times, what was covered, did they check blood pressure, prescribe treatments, check medication, give you any advice...]

What happened the last time they visited the doctor – did they talk about the stroke

Does anyone go to the doctor with them – if so who

#### **Community services**

Whether they have seen any other health professions since the stroke?

District nurse, day hospital, physiotherapist. If yes, what for, what did they do/talk about?]

#### **Tests and investigations**

Have they had any tests or investigations for your stroke

Blood pressure checks, diabetes, cholesterol, hospital tests

#### **Medication**

Whether they have been given any medication for the stroke

If yes – what are the medications, what are they for – check preventive medications, how do they get hold of them, how do they take them, do they have any strategies for remembering them, advice about taking medication

If not already mentioned, does anyone help you with your medication, how do they help?

#### **Prevention advice**

Whether they have been given any advice about how to prevent future strokes?

If yes – what sort of advice, who gave it to them, when did they get it, what did it say, what did they think of it, did they make any changes as a result of the advice

If person has help getting to doctor/taking medication did that person have any information after the stroke?

**Written information**

Whether they have been given any written information about preventing further strokes.

If yes – what sort of advice, who gave it to them, when did they get it, what did it say, what did they think of it, did they make any changes as a result of the advice.

Was the advice designed specifically for them? How did you know this? If yes, what sort of information was specifically about you

**Unanswered questions**

Whether there is anything they would like to know more about, questions they would like to ask your doctor.

Whether they have asked the doctor these questions, whether they would ask them, whether this info was covered in the advice they had?

*Patient understanding of stroke secondary prevention***Can you tell me a bit about what you know about your stroke?**

Prompts:

**Why the stroke happened**

Do you know why you had a stroke?

[prompt subjective – your stroke not why people have strokes in general, how do you this?]

**Risk factors for stroke**

Is there anything else that contributed to your stroke?

[what sorts of things - prompt smoking, having high blood pressure. How do you know this?]

**The future**

How do you see your future in terms of your stroke?

[is stroke over with now? Why see future like this – is it because you have/haven't fully recovered yet?]

If stroke not over/not recovered, do you think the stroke will ever been over and done with? [if yes, when, how will you know?]

Do you think it is possible to have more strokes in the future?

[why think this, who told this]

Do you worry about having another stroke?

**Preventing future strokes**

Is there anything that can be done to prevent further strokes (general)

[if yes prompt what sorts of things, if no prompt why not]

Is there anything that can be done to prevent you having another stroke?

[what sorts of things are you doing - medication, will they work, how will they work. Do you think these things will work? How do you know]

Is there anything the doctors can do to prevent you having another stroke?

[what sorts of things can be done, which of these are they doing, will they work?]

How important is it to try and prevent further strokes?

### *Specific Questions on the intervention*

If not already mentioned...

**As part of our research project you were meant to have received a pack about preventing future strokes. Did you receive a secondary prevention pack?**

Prompts:

#### **Delivery**

How did you get hold of the pack?

When did you get the pack?

#### **Content**

What was in the pack?

What did the pack tell you?

[prompt did it say anything about blood pressure, smoking, diabetes]

What did you think of the pack?

[could you understand the information, how helpful was it]

Was there anything specific about the pack that you liked/disliked?

Did the pack answer any of the questions you had about your stroke?

[if yes what were the questions? If no, what questions would you like to ask?]

#### **Actions taken**

What did you do with the pack?

[did you keep it, where do you keep it?]

Have you ever shown the pack to your doctor?

[what happened, what did he/she think of it?]

Do you do anything specific as a result of the information provided in the pack?

[did you see the doctor, change what you eat, give up smoking, start taking any medication, take up exercise?]



## **Appendix 7. Intervention Plans**

This appendix includes the individualised secondary prevention plans for patients and professionals:

Patient initial plan (yellow)

Patient 3-month follow up plan (green)

Patient 6-month follow up plan (peach)

Professional initial plan (yellow)

Professional 3-month follow up plan (green)

Professional 6-month follow up plan (peach)

A covering letter is provided with each plan. The plans have been formatted to fit into this thesis. Original patient plans are presented using a minimum font size of 16 point Arial font. Patient plans are folded in half together with specific numbered laminated information sheets (Appendix 9). Plans and information sheets are provided in a clear plastic A5 wallet with the patient's name on the front.

Original professional plans have a minimum font size of 8 point Arial font. The professional plan is a single sided sheet folded in half to make an A5 booklet, designed to fit into the patient's general practice notes.

Mr P Patient  
1 The High Street  
London  
SE1 1AB

12 January 2007

Dear Mr P Patient

### **Keeping well after stroke**

This is your **plan** for **keeping well** after stroke. The plan will help you prevent any further strokes. It was designed **specifically for you** using information about the type of stroke you had. If there is anything in the plan that you don't understand, please contact your doctor or nurse.

Your doctor or nurse has probably already told you there is a **chance** you could have **another stroke** in the future. No one knows what the risk is for you personally, but the chance may be as high as **1 in 5** in the **next year**. But **don't panic!** There is quite a lot that you can do to prevent further strokes.

What to do now:

**Read the next page.** There is a **list** of things you and your doctor can do to help **prevent further strokes**. For each of these things on your list, read the numbered sheets for more advice.

Keep your plan somewhere safe. It is a good idea to **show** your **plan** to your **friends, relatives** or **carers** so you can talk about what you are doing to prevent further strokes. Take it to your **doctor** or nurse next time you see them.

**Yours sincerely**

**The Stroke Research Team**



**Keeping well after stroke**  
**Plan for Mr P Patient: 15 January 2007**

Things which increase your chance of another stroke	What you should do:	Read sheet no.
High blood pressure. Your last recorded blood pressure was: 170/95	Take your: Ramipril: 100mg twice a day. Cut down on salt and salty foods	1, 3, 4
Atrial Fibrillation	ask your doctor if you should take Warfarin	5, 6, 9
High Cholesterol. Your last recorded cholesterol was 6.2mmol/L	keep your take your Simvastatin 50mg/day	13, 14
Smoking: 20 cigarettes a day	You need to try to give up smoking	15
Heavy drinking: 42 units alcohol a week	You need to cut down on the amount of alcohol you drink	16

Keep this pack somewhere safe in case you want to read it again in the future. We'll contact you again in 3 months time to update the plan.



Mr P Patient  
1 The High Street  
London  
SE1 1AB  
12 January 2007

Dear Mr Patient

**Keeping well after stroke  
(3-month update)**

This is your **3-month plan for keeping well** after your stroke. The plan will help you prevent further strokes. It was designed **specifically for you** using information about the type of stroke you had. If there is anything in the plan that you don't understand, please contact your doctor or nurse.

What to do now:

**Read the next page.** There is a **list** of things you and your doctor can do to help **prevent further strokes**. For each of these things on your list, read the numbered sheets for more advice.

Keep your plan somewhere safe. It is a good idea to **show your plan** to your **friends, relatives** or **carers** so you can talk about what you are doing to prevent further strokes. Take it to your **doctor or nurse** next time you see them.

Don't forget to get **regular blood pressure checks** at your GP surgery.

**Yours sincerely**

**The Stroke Research Team**

# Keeping well after stroke Plan for Mr P Patient: 12 January 2007

Things which increase your chance of another stroke:	The last time we visited you:	What this means:	What you need to do now:	Read sheets:
High blood pressure. Before your stroke your blood pressure was: 170/80	you were taking tablets to lower your blood pressure. Your blood pressure was: 130/70. You had tried cutting down on salt and salty foods	you have controlled some of the things which can cause strokes, but there is still more you can do	keep taking your blood pressure tablets. Cut down on salt and salty foods	1, 4
Atrial Fibrillation (irregular heartbeat)	you were taking Aspirin		check with your doctor that you are taking the right medication	5, 6, 9
High cholesterol (a type of fat in your blood). When you had your stroke your cholesterol was: 4.8 mmol/l	you were taking tablets to lower your cholesterol. Your last cholesterol was: 5 mmol/l. You had tried cutting down on fat and fatty foods		keep taking your cholesterol tablets. Cutting out fat and fatty foods	13, 4

Plan continued (page 2)

Things which increase your chance of another stroke:	The last time we visited you:	What this means:	What you need to do now:	Read sheets:
Smoking. When you had your stroke you were smoking 20 cigarettes a day	you had increased your smoking: 30 cigarettes a day	you have controlled some of the things which can cause strokes, but there is still more you can do	you need to try and give up, or at least cut down on the amount you smoke	15
Heavy drinking: 42 units of alcohol a week	your drinking was OK: 28 units of alcohol a week		you're doing fine but don't let your drinking increase again	



Mr P Patient  
1 The High Street  
London  
SE1 1AB  
12 January 2007

**Dear Mr Patient**

**Keeping well after stroke**  
(6-month update)

This is your **6-month plan for keeping well** after your stroke. The plan will help you prevent further strokes. It was designed **specifically for you** using information about the type of stroke you had. If there is anything in the plan that you don't understand, please contact your doctor or nurse.

What to do now:

**Read the next page.** There is a **list** of things you and your doctor can do to help **prevent further strokes**. For each of these things on your list, read the numbered sheets for more advice.

Keep your plan somewhere safe. It is a good idea to **show** your plan to your **friends, relatives or carers** so you can talk about what you are doing to prevent further strokes. Take it to your **doctor or nurse** next time you see them.

Don't forget to get **regular blood pressure** checks at your GP surgery.

**Yours sincerely**

**The Stop Stroke Research Team**

**Keeping well after stroke**  
**Plan for Mr P Patient: 12 January 2007**

<b>Things which increase your chance of another stroke</b>	<b>3 months ago:</b>	<b>Last time we visited you:</b>	<b>What this means:</b>	<b>What you need to do now:</b>	<b>Read sheets:</b>
High blood pressure. Before your stroke your blood pressure was: 170/80	you were taking tablets to lower your blood pressure. Your blood pressure was: 130/70. You had tried cutting down on salt and salty foods	you were taking tablets to lower your blood pressure. Your blood pressure was: 140/70. You had tried cutting down on salt and salty foods	Good news, you are doing all you can to prevent further strokes	keep taking your tablets. Keep watching what you eat	
Atrial Fibrillation (irregular heartbeat)	you were taking Aspirin	you were taking Warfarin		keep taking your Warfarin	
High cholesterol (a type of fat in your blood). When you had your stroke your cholesterol was: 4.8 mmol/l	you were taking tablets to lower your cholesterol. Your last cholesterol was: 5 mmol/l. You had tried cutting down on fat and fatty foods	you were taking tablets to lower your cholesterol. Your last cholesterol was: 5 mmol/l. You had tried cutting down on fat and fatty foods		keep taking your tablets. Keep watching what you eat	

**Plan continued (page 2)**

<b>Things which increase your chance of another stroke</b> Smoking. When you had your stroke you were smoking 20 cigarettes a day Heavy drinking: 42 units of alcohol a week	<b>3 months ago:</b>  you had increased your smoking: 30 cigarettes a day  Your drinking was OK: 4 units of alcohol a week	<b>Last time we visited you:</b>  You had given up smoking  Your drinking was OK: 4 units alcohol a week	<b>What this means:</b>  Good news, you are doing all you can to prevent further strokes	<b>What you need to do now:</b>  It's a real achievement, so whatever you do don't start smoking again.  you're doing fine but don't let your drinking increase again	<b>Read sheets:</b>
--	--	--	--	---	---------------------



Dr G. Practitioner  
The Surgery  
10 Healthy Road  
London  
S1 DEF

12 January 2007

Dear Dr Practitioner

### **Stop Stroke Secondary Prevention Plan**

Please find attached the Stop Stroke Secondary Prevention plan for your patient Mr P Patient. Mr P Patient had a stroke on 5/5/2006 and has consented to take part in the Stop Stroke Trial. A patient version of this plan has been sent to Mr P Patient. He has been advised to get his blood pressure checked within the next two weeks and to contact you if he has any queries about secondary prevention.

We will contact you in 3 months time to update the plan. If in the meantime you have any queries about Stop Stroke please contact the South London Stroke Register on 020 7848 6612 or email [stroke-register@kcl.ac.uk](mailto:stroke-register@kcl.ac.uk).

**Yours sincerely**

**The Stroke Research Team**

**Stop Stroke**  
Secondary Prevention Plan  
for  
Mr P Patient

Date of birth: 17/1942  
Date of stroke: 5/5/2006

This plan was produced using data from the  
South London Stroke Register on the 12 January 2007

Risk Factor	Assessment	Measure	Comment	Medication prescribed	RCP guidelines (Update 2004)
Previous stroke	ischaemic stroke, read codes G73 (version 4.3); G66. (version 5)		no known contraindications to antiplatelets	Aspirin: 100 mg/day, read codes: 8B63-1 (version 4.3); 8B63 (version 5)	All patients with ischaemic stroke or TIA who are not on anticoagulation should be taking an antiplatelet agent, ie aspirin (50-300mg) daily, or clopidogrel, or a combination of low-dose aspirin and dipyridamole modified release (MR). Where patients are aspirin intolerant an alternative antiplatelet agent (eg clopidogrel 75 mg daily or dipyridamole MR 200 mg twice daily) should be used.
Blood pressure	history of hypertension prior to stroke, read codes: G31 (version 4.3); G20 (version 5)	last recorded blood pressure: 170/95		Ramipril 100mg twice a day	All patients should have their blood pressure checked, and high blood pressure persisting for over two weeks should be treated. The British Hypertension Society guidelines are: In non-diabetic people with hypertension the optimal blood pressure treatment goals are systolic blood pressure <140mmHg and diastolic blood pressure <85mmHg. Further reduction of blood pressure should be undertaken using a thiazide diuretic (eg indapamide or bendrofluazide) or an ACE inhibitor (eg perindopril or ramipril) or preferably a combination of both, unless there are contraindications.
Cholesterol	history of high cholesterol prior to stroke, read codes: C521 (version 4.3); C320 (version 5)	last recorded cholesterol: 6.2mmol/L		Simvastatin 50mg/day	Treatment with a statin (eg 40mg simvastatin) should be given to patients with ischaemic stroke or TIA, and total cholesterol of >3.5mmol/L, unless contraindicated.
Diabetes	no history of diabetes prior to stroke	HbA1c not known			For patients with diabetes mellitus and high blood pressure the optimal goals of blood pressure control are 130/80.
Atrial fibrillation	atrial fibrillation diagnosed on ECG at time of stroke, read codes: G67 (version 4.3); G573 (version 5)		no known contraindications for Warfarin. Heavy drinker.	Aspirin: 100 mg/day	Anticoagulation should be started in every patient with persistent or paroxysmal atrial fibrillation (valvular or non valvular) unless contraindicated. Anticoagulants should not be used for patients in sinus rhythm unless there is a major source of cardiac embolism. Anticoagulants should not be started until brain imaging has excluded haemorrhage, and usually not until 14 days have passed from the onset of an ischaemic stroke.
Smoking	current smoker	20 cigarettes / day			All patients should be given appropriate advice on: i) stopping smoking; ii) regular exercise; iii) diet and achieving a satisfactory weight; iv) reducing the intake of salt; v) avoiding excess alcohol.
Alcohol use	heavy drinker	42 units alcohol / week			
Obesity	not obese at time of stroke				

Dr G. Practitioner  
The Surgery  
10 Healthy Road  
London  
S1 DEF

12 January 2007

Dear Dr Practitioner

**Stop Stroke Secondary Prevention Plan  
(3-month update)**

Please find attached the updated Stop Stroke secondary prevention plan for your patient Mr P Patient. Mr P Patient had a stroke on 17/2/2006 and has consented to take part in the Stop Stroke Trial. The plan contains information on his risk factors including cardiovascular read codes where appropriate (Meditel Emis version 4.3 and Vamp, Emis version 5, Seetec).

Fred Livermore has been advised to get regular blood pressure checks and to contact you if he has any queries about secondary prevention.

We will contact you in 3 months time to update the plan. If in the meantime you have any queries about Stop Stroke please contact the South London Stroke Register on 020 7848 6612 or email [stroke-register@kcl.ac.uk](mailto:stroke-register@kcl.ac.uk).

**Yours sincerely**

**The Stroke Research Team**



This plan was produced using data collected by the  
South London Stroke Register on the 12 January 2007

**Stop Stroke Secondary Prevention Plan**  
3-month follow up for Mr P Patient

Date of birth: 17/11/1935

Date of stroke: 17/2/2006

Risk Factor	3-month Assessment	3-month measures	Comment	Management at 3 months	RCP guidelines (update 2004)
Previous stroke	ischaemic stroke, read codes: G73 (version 4.3); G66. (version 5)		No known contraindications for antiplatelets.	taking aspirin, read codes: 8B63-1 (version 4.3); 8B63 (version 5)	All patients with ischaemic stroke or TIA who are not on anticoagulation should be taking an antiplatelet agent, ie aspirin (50-300mg) daily, or clopidogrel, or a combination of low-dose aspirin and dipyridamole modified release (MR). Where patients are aspirin intolerant an alternative antiplatelet agent (eg clopidogrel 75 mg daily or dipyridamole MR 200 mg twice daily) should be used.
Blood pressure	history of hypertension, read codes: G31 (version 4.3); G20 (version 5)	Blood pressure at 3 months: 130/70		taking antihypertensives has not cut down on salt and salty foods	All patients should have their blood pressure checked, and high blood pressure persisting for over two weeks should be treated. The British Hypertension Society guidelines are: In non-diabetic people with hypertension the optimal blood pressure treatment goals are systolic blood pressure <140mmHg and diastolic blood pressure <85mmHg. Further reduction of blood pressure should be undertaken using a thiazide diuretic (eg indapamide or bendrofluazide) or an ACE inhibitor (eg perindopril or ramipril) or preferably a combination of both, unless there are contraindications.
Cholesterol	history of high cholesterol, read codes: C521 (version 4.3); C320 (version 5)	Cholesterol at 3 months: 5mmol/L		taking a statin has not cut down on fat or fatty foods	Treatment with a statin (eg 40mg simvastatin) should be given to patients with ischaemic stroke or TIA, and total cholesterol of >3.5mmol/L, unless contraindicated.
Diabetes	no recorded history of diabetes				For patients with diabetes mellitus and high blood pressure the optimal goals of blood pressure control are 130/80.
Atrial fibrillation	history of atrial fibrillation, read codes: G67 (version 4.3); G573 (version 5)		No known contraindications for Warfarin.	taking aspirin, read codes: 8B63-1 (version 4.3); 8B63 (version 5)	Anticoagulation should be started in every patient with persistent or paroxysmal atrial fibrillation (valvular or non valvular) unless contraindicated. Anticoagulants should not be used for patients in sinus rhythm unless there is a major source of cardiac embolism. Anticoagulants should not be started until brain imaging has excluded haemorrhage, and usually not until 14 days have passed from the onset of an ischaemic stroke.
Smoking	Patient had increased amount smoked	30 cigarettes a day			All patients should be given appropriate advice on: i) stopping smoking; ii) regular exercise; iii) diet and achieving a satisfactory weight; iv) reducing the intake of salt; v) avoiding excess alcohol.
Alcohol use	Patient had reduced to moderate drinking	28 units alcohol a week			
Obesity	not obese at the time of stroke	BMI not measured at 3 months		not applicable	

Dr G. Practitioner  
The Surgery  
10 Healthy Road  
London  
S1 DEF

12 January 2007

Dear Dr Practitioner

**Stop Stroke Secondary Prevention Plan  
(6-month update)**

Please find enclosed the updated Stop Stroke Secondary Prevention plan for your patient Mr P Patient. Mr P Patient had a stroke on 3/1/2006 and has consented to take part in the Stop Stroke Trial. The plan contains information on heris risk factors 6 months post stroke including cardiovascular read codes (Meditel, Emis version 4.3 and Vamp, Emis version 5, Seetec)

Mr P Patient has been advised to get regular blood pressure checks and to contact you if she has any queries about secondary prevention.

If in the meantime you have any queries about Stop Stroke please do not hesitate to contact the South London Stroke Register on 020 7848 6612 or email [stroke-register@kcl.ac.uk](mailto:stroke-register@kcl.ac.uk).

**Yours sincerely**

**The Stroke Research Team**



**Stop Stroke Secondary Prevention Plan  
6-month follow up for Mr P Patient**

Date of birth: 27/3/1956  
Date of stroke 3/1/2006

This plan was produced using data collected by the  
South London Stroke Register on the 12 January 2007

Risk Factor	6 month Assessment	6 month measures	Comment	Management at 6 months	RCP guidelines (update 2004)
Previous stroke	ischaemic stroke, read codes G73 (version 4.3); G66 (version 5)		No known contraindications for aspirin	Taking Warfarin	All patients with ischaemic stroke or TIA who are not on anticoagulation should be taking an antiplatelet agent, ie aspirin (50-300mg) daily or clopidogrel or a combination of low-dose aspirin and dipyridamole modified release (MR). Where patients are aspirin intolerant an alternative antiplatelet agent (eg clopidogrel 75 mg daily or dipyridamole MR 200 mg twice daily) should be used.
Blood pressure	history of hypertension, read codes G31 (version 4.3); G20 (version 5)	blood pressure at 6 months: 130/70		Taking antihypertensives has tried to cut down on salt or salty foods	All patients should have their blood pressure checked and high blood pressure persisting for over two weeks should be treated. The British Hypertension Society guidelines are in non-diabetic people with hypertension the optimal blood pressure treatment goals are systolic blood pressure <140mmHg and diastolic blood pressure <85mmHg. Further reduction of blood pressure should be undertaken using a thiazide diuretic (eg indapamide or bendroflumazide) or an ACE inhibitor (eg perindopril or ramipril) or preferably a combination of both, unless there are contraindications.
Cholesterol	history of high cholesterol, read codes: C521 (version 4.3); C320 (version 5)	cholesterol at 6 months: 5mmol/L		taking statins has tried to cut down on fatty foods	Treatment with a statin (eg 40mg simvastatin) should be given to patients with ischaemic stroke or TIA, and total cholesterol of >3.5mmol/L, unless contraindicated.
Diabetes	No history of diabetes	HbA1c was not measured by the interviewer at 6 months.		not currently on medication for diabetes	For patients with diabetes mellitus and high blood pressure the optimal goals of blood pressure control are 130/80.
Atrial fibrillation	history of atrial fibrillation, read codes: G67 (version 4.3); G573 (version 5)		No known contraindications for Warfarin	taking Warfarin	Anticoagulation should be started in every patient with persistent or paroxysmal atrial fibrillation (valvular or non valvular) unless contraindicated. Anticoagulants should not be used for patients in sinus rhythm unless there is a major source of cardiac embolism. Anticoagulants should not be started until brain imaging has excluded haemorrhage, and usually not until 14 days have passed from the onset of an ischaemic stroke.
Smoking	patient has given up smoking	0 cigarettes / day			All patients should be given appropriate advice on: i) stopping smoking; ii) regular exercise; iii) diet and achieving a satisfactory weight; iv) reducing the intake of salt; v) avoiding excess alcohol.
Alcohol use	patient has reduced to moderate drinking	20 units alcohol / week			
Obesity	not obese at the time of stroke	BMI not measured by the interviewer at 6 months		has cut down on fatty foods	



## **Appendix 8. Proposal for developing intervention components**

### **Background**

Stop Stroke research has identified a need for more appropriate information and guidelines to be provided to health professionals and patients on how to manage their risk factors. Current information tends to be generalised, often not relevant to the needs and concerns of the individual patient and not provided at a time when secondary prevention is priority (Wiles et al., 1998). Thus current care may be missing opportunities to inform patients about secondary prevention. This intervention aims to overcome previous inadequacies by providing individualised information and guidelines on management to patients and professionals and timely reminders to those whose risk factor management is less than optimal.

**Aim: To develop system of providing management plans and follow up reminders for patients and health professionals tailored to the individual patient using a chronic disease register.**

### **Objectives:**

1. Redesign SLSR questions for collection of data on patient characteristics and risk factors to be used in the management plan.
2. Design a hard copy individualised management plan (or plans) for patients integrating data from the SLSR and RCP guidelines on best management practice
3. Design a hard copy individualised management plan (or plans) for health professionals integrating data from the SLSR and RCP guidelines on best management practice
4. Design individualised reminder letters to inform patients and health professionals when patients need follow up or monitoring of their risk factors
5. Develop a computer based system of converting SLSR data into hard copy individualised management plans and reminder letters for patients and health professionals

**Redesign SLSR questions for collection of data on patient characteristics and risk factors to be used in the management plan.**

The SLSR currently collects data on a range of patient sociodemographic and clinical characteristics including pre and post stroke clinical and behavioural risk factors, treatments, and resource use. Data are currently collected at the time of stroke, 3 months, 12 months and annually post stroke. These data can be used to provide information on individuals' risk factors and appropriate treatments. However some of the questions are not currently detailed enough to draw conclusions about where secondary prevention should be targeted. It would be useful to know the patient's actual blood pressure rather than a blood pressure category. It would also be useful to know the patient's cholesterol levels. Current resource questions ask about general follow up rather than stroke related follow up or prevention related follow up. Current medication questions ask about medication patients 'are on' and do not distinguish between medication prescribed vs medication actually taken. Data on smoking status is currently collected but not on the quantity smoked or on attempts to quit. By adapting the



questions in the SLSR additional information could be collected useful for patient management , in particular more detailed information on:

- type of information sought by patients and provided by health professionals
- type of follow up (whether stroke related) and secondary prevention issues covered
- blood pressure and cholesterol measurements
- concordance issues, including medication taken as well as medication prescribed
- attempts to change behaviour (e.g. number of cigarettes smoked, attempts to quit smoking)

Current questionnaires will be revised and feedback on questionnaire revisions will be gained from clinicians, statisticians, register staff and field workers. The questionnaires will be piloted for appropriateness with the South London Patient Advisory Group.

### **To design a hard copy individualised management plan for patients integrating data from the SLSR and RCP guidelines on best management practice**

Current information provided to patients tends to be in leaflet or booklet form providing general advice about stroke, risk factors (smoking cessation leaflets, dietary advice, hypertension management). However generalised information is often not relevant to the patient. Generalised information (because it is often necessary to cover so many diverse issues) often does not include details relevant to the individual patient (Wiles et al., 1998). Current advice also often makes assumptions about patients' understanding of the health system, and process of follow up (Redfern et al., 2001). Treatment plans will be designed for the management of each risk factor (e.g. separate plans on aspirin use, high blood pressure treatments, blood pressure monitoring for non-hypertensive patients). Different management plans will be produced to take into account differences between patients, for example [NOT SURE ABOUT THIS, NEED INPUT FROM CLINICIANS] for African Caribbean patients a section on diet will include information on cooking with African Caribbean foods rather than on advice relating to a traditional British diet. Equally patients who are severely disabled will have different advice on collecting prescriptions compared to those who are independent.

Plans will be written in lay terminology and in a font size which is easy to see even with poor eyesight. Each plan will be formatted to an A5 size so that it can be slotted into a folder or pack and so that additional sections can be added if and when required. Leaflet design, readability and content will be piloted among the South London Stroke Patient Advisory Group.

- Hard copy management plans will be designed for patients to provide to individualised information on:
- the type of stroke the patient has had
- risk factors: diagnoses, investigations and test results and how management of these can help prevent a subsequent stroke
- lay guidelines on risk factor management (based on RCP lay guidelines) including explanation of treatments and concordance issues
- health care processes (how to get a prescription, appointment dates/times/location, how to make an appointment)
- the health care team (who is responsible for care including contact details)

### **To design hard copy individualised management plans for health professionals integrating data from the SLSR and RCP guidelines on best management practice.**



Guidelines on the best practice for secondary prevention management of stroke patients have been produced by the Royal College of Physicians (Royal College of Physicians 2000). However RCP guidelines may not be accessible to the health professional at the point of contact with the patient. Providing individualised guidelines to health professionals which can be placed in patients' notes so that they are to hand in consultations may help get evidence into practice. Equally, medical decision making is dependent on individual patient information (e.g. on risk factors and treatments) being available to the health professional at the point of contact. The information provided in current referral letters is variable. A North Ireland study reported that only 17% of letters sent from hospital to GP gave details of the risks associated with treatments or the need for regular GP monitoring (Corry et al., 2000). A more detailed description of patients' risk factors and treatment generated from SLSR data may help inform decision making. Plans will be piloted with hospital doctors and general practitioners for readability, and content.

Hard copy management plans will be designed for health professionals providing information and guidelines on:

- stroke subtype
- risk score (evaluation of how high a patients' risk is and the effect of risk factor management on recurrence)
- details of risk factors and risk factor change
- test results and investigations
- RCP guidelines on management of risk factors
- Current medication (prescribed medication, contraindications to medication and concordance issues)
- Lifestyle issues
- Recommended follow up and monitoring plan

**To design an individualised reminder letter to inform patients and health professionals that patients need follow up and monitoring of their risk factors.**

The majority of patients receive at least one follow up appointment within 3 months of their stroke, however over half do not see a stroke specialist and 14% do not see a doctor at all (Redfern et al., submitted). Equally a one-off visit may not be enough to ensure that secondary prevention issues are addressed. Although some patients get organised stroke secondary prevention, others rely on opportunistic or lay management. (Redfern et al., 2000). Individualised reminder letters will inform patients and professionals when risk factors need monitoring (e.g. patients with high blood pressure need check ups until their blood pressure is adequately controlled and then annually thereafter). Individualised reminder letters will be sent out before an appointment is required giving details of risk factors needing attention (non managed risk factors) and the appropriate course of action (make an appointment with hospital doctor, GP, practice nurse).

**To develop a computer based system for converting SLSR data into hard copy individualised management plans and reminder letters for patients and health professionals**



After data collection, SLSR data are currently entered into a database using EpiInfo and analysed for research purposes using statistical software (STATA). In order to make the system practical, user friendly and generalisable to other organisations or disease groups this study aims to develop a system using computer software which is widely available and does not require specialist skills to use. The proposed system uses STATA and Microsoft Word.

The proposed system combines STATA and Microsoft Word software packages and is divided into 2 parts:

*Creating a management database:* Using STATA, Algorithms will be designed to code existing variables into categories which define patients' risk factors and their appropriate treatments (e.g. patients with atrial fibrillation can be categorised into those who are appropriate for anticoagulants and those appropriate for antiplatelets depending on their comorbidities and contraindications to medication). These new variables together with data on patient characteristics (e.g. age, sex, ethnicity, disability date of stroke, resource use) saved into a Word (or text friendly) database. Although this system will be designed in STATA, but most statistical packages including SPSS for Windows would have the capability to produce a management file using the algorithms. Therefore the system would be generalisable even with different databases using different statistical software.

*Creating a mail merge template:* Patient and Health Professional Management Plans and reminder letters will be created as Mail merge document templates in Microsoft Word. Individual patient variables from the management database will form merge fields which can be inserted into the template. Appropriate information and guidelines can be inserted into the document using word fields and logic statements (e.g. if [blood pressure >160/90] insert text "your blood pressure is too high"). Separate mail merge documents can be created for each type of risk factor. Mail merge has a filter facility which can be used to ensure documents are only produced for those patients who need them (e.g. a high blood pressure treatment plan is only produced for patients with hypertension). Filtering can also be used to create reminder letters prior to appointment dates and at 3 month, 6 month and yearly intervals. Given that Microsoft word is widely available, it would be possible to send mail merge documents electronically to patients or health professionals if preferred.

**Resources:**

- Computing facilities: Epi Info, STATA, Microsoft Word
- Paper for management plans and reminder letters
- Folders or packs for management plans
- Envelopes and postage costs for sending reminders

**Time Frame:**

It is estimated that design of the templates and database would take approximately 4-6 weeks. Piloting of the plans would take a further 1-2 months.

**Staff:**

- Researcher to develop computer based system
- Statistical support to ensure the STATA commands are accurate
- Clinician support in the development of the management algorithm

## References:

1. Wiles R, Pain H, Buckland S, McLellan L, 1998. Providing appropriate information to patients and carers following stroke *Journal of Advanced nursing*: 28; 794-801
2. Redfern, J, McKevitt C, Wolfe C, 2001. Communicating secondary prevention advice: a qualitative investigation of current practice. *Cerebrovascular diseases*: (11, S4, 15)
3. Corry M, Bonner G, McEntee S, Dugan J, Domhainnall M, 2000. Hospitals do not inform GPs about medication that should be monitored.
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5. Redfern J, McKevitt, C Rudd A, Wolfe CDA, (submitted). Health care after stroke: opportunities for secondary prevention.
6. Royal College of Physicians, 2000. National Clinical Guidelines for Stroke. London: Royal College of Physicians.

## **Appendix 9. Patient Information Sheets**

This Appendix contains the patient information sheet component of the Stop Stroke intervention. Each sheet is numbered and links to the corresponding number on the individualised patient plans. Each patient receives only the information sheets relevant to him or her. The sheet size has been modified to fit into this thesis. Each sheet is single or double-sided A5 and printed on white paper that is subsequently laminated.

The minimum font size is 16 point Arial font. There are 21 sheets in total:

High Blood Pressure.	Diabetes Diet
Haemorrhage	Diabetes Medicine
Blood pressure tablets	High cholesterol
Healthy eating	Cholesterol tablets
Stroke advice	Smoking
Atrial Fibrillation	Alcohol men
Warfarin	Alcohol – women
Aspirin	Obesity
Aspirin, Dipyridamole and	Exercise
Clopidogrel	Blood pressure
Diabetes	Cholesterol



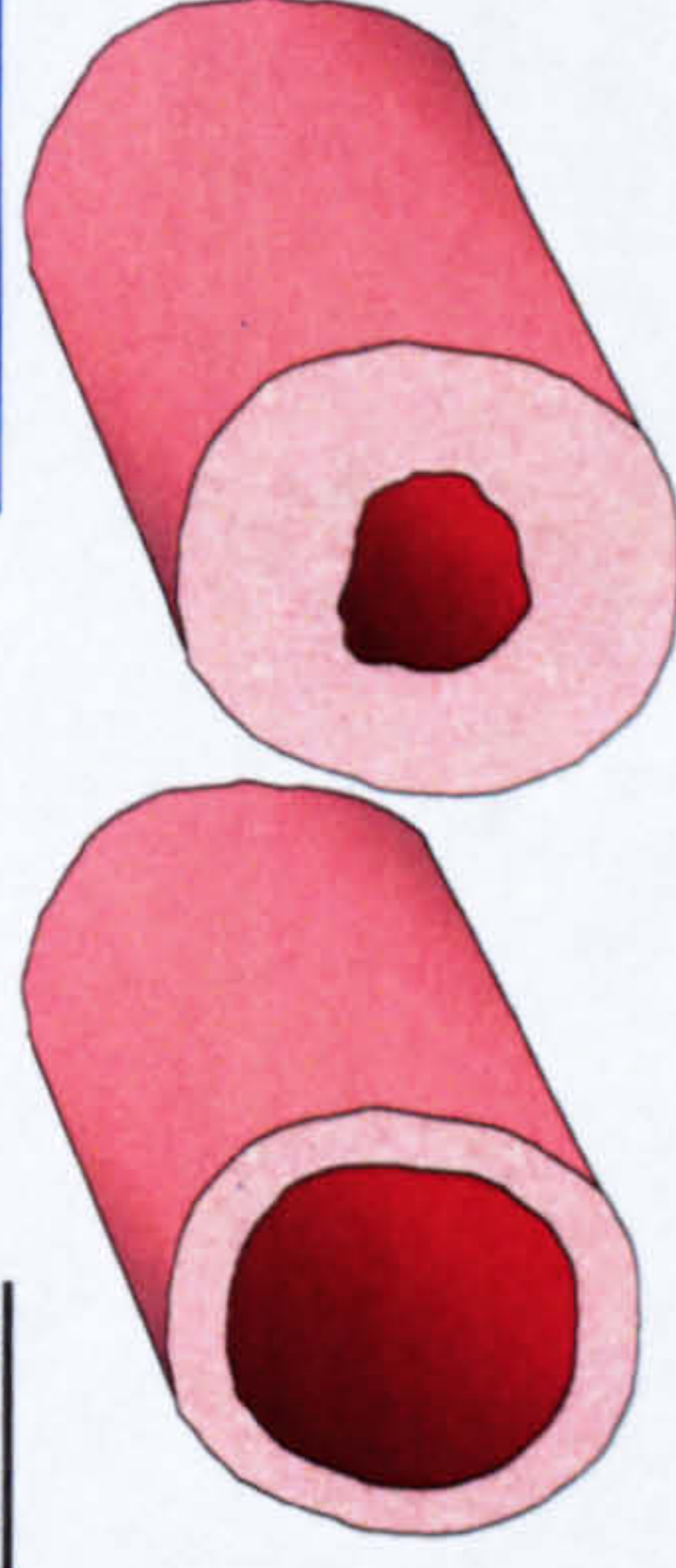
## 1. High blood pressure advice sheet

You have high blood pressure (hypertension). Keeping your **blood pressure controlled** (within safe limits) is the most important thing you can do to help **prevent further strokes**.

Over time **high blood pressure** can **damage** your **blood vessels**. The walls thicken making the blood vessels narrow and weak. They may become blocked, or can even burst, causing a stroke.

Healthy blood vessel

Blood vessel narrowed due to high blood pressure



You may **think you can tell** when your blood pressure is too high (some people say they get headaches, nose bleeds, feel numb or tingly). But just because you don't have symptoms, doesn't mean your blood pressure is OK. The only way to be sure is to **get it checked** by a **doctor or nurse**.

**PTO**

Blood pressure machines give you 2 numbers. The first is the pressure when your blood is pumped out of the heart. The second is the pressure when your heart is relaxed. Experts say your **blood pressure** should be **no higher than 140/85**. If you also have **diabetes** your blood pressure should be no higher than **130/80**.

You should get your **blood pressure checked** at least **every 6 months**. If it's not controlled you may need to see the GP more often. If you haven't had your blood pressure checked since your stroke, you should have this done at your GP surgery as soon as possible.

You can buy kits to test your blood pressure at home (from large chemists) but they aren't cheap (about £100) and are not available on the NHS. If you want to buy one, ask your doctor for advice.

We don't know exactly what causes high blood pressure, but it doesn't go away even when you feel relaxed. High blood pressure can be **lowered with tablets**. You can also treat it and help prevent it getting any worse by **reducing** the amount of **salt** and **salty foods** you eat.

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## 2. Haemorrhage advice sheet

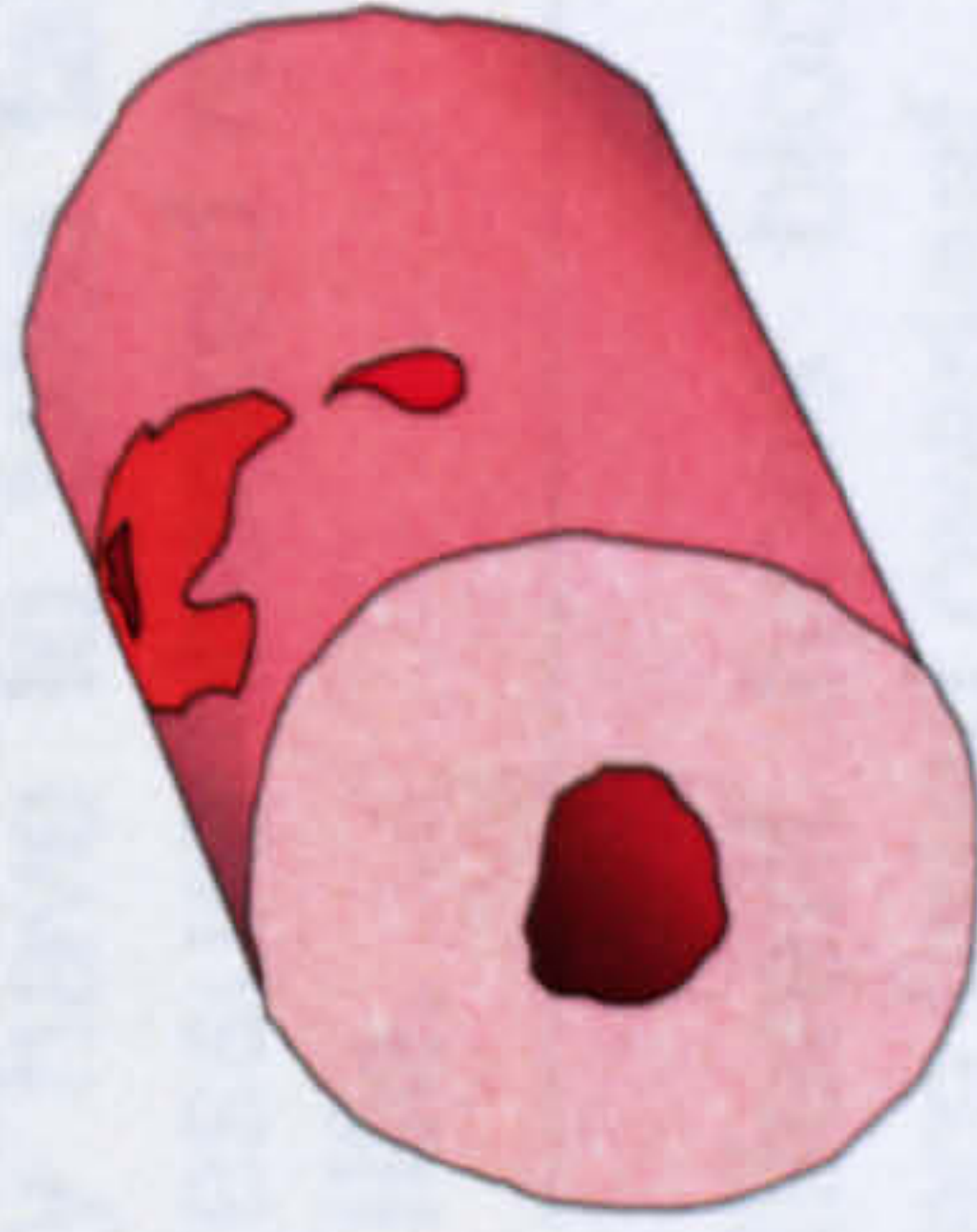
You have had a **haemorrhage (a bleed)**. This means that a blood vessel in or near your brain started bleeding or burst and the blood supply to part of your brain stopped.

If the blood supply stops parts of the **brain** become **damaged** or die. Because your brain controls the rest of your body, many different body functions can be affected (e.g. **loss of speech, weakness** in one side of the body).

No one knows why your stroke happened on the day it did, but it may have been an accident waiting to happen. Most strokes like yours are linked to **high blood pressure**. High blood pressure causes damage to your **blood vessels** making them **weak** and more likely to bleed.

### Bleeding blood vessel

narrow blood  
vessel caused by  
high pressure



PTO

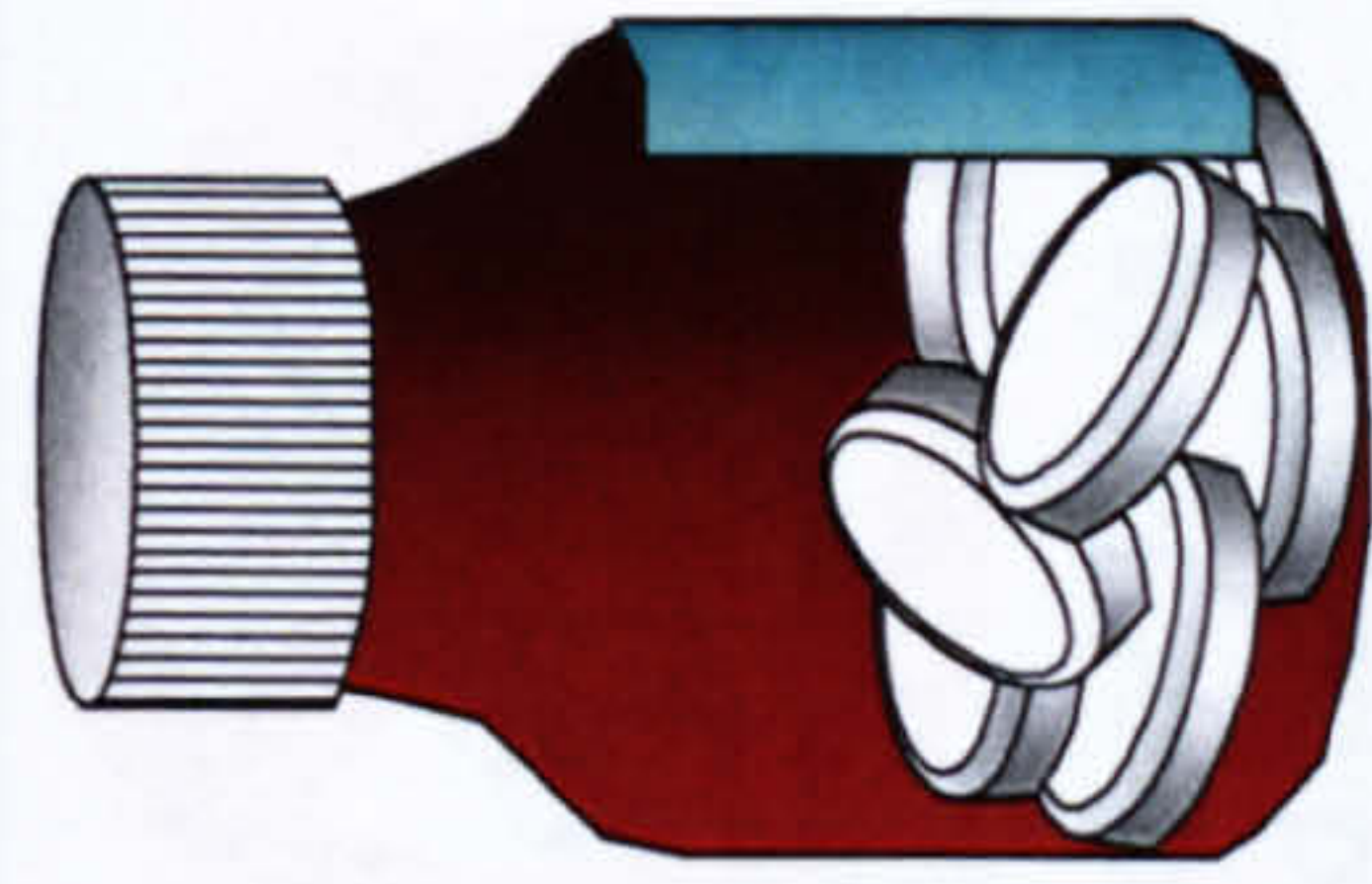
## Preventing strokes in the future

Having a stroke is a sign that your blood vessels may be damaged. They may have been damaged for many years without you even knowing about it. So it's even more important to look after your blood vessels from now on. This means look after your **blood pressure** and **cholesterol**, watching your **weight**, not **smoking** and keeping **diabetes** under control.

- Keep your blood vessels healthy
- Get your blood pressure **checked** regularly

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### 3. Blood pressure tablets

You have been prescribed **tablets** for your **blood pressure** (antihypertensive tablets).

These tablets will **help prevent another stroke** by lowering your blood pressure.

If you have been taking blood pressure tablets for more than a month, and your blood pressure is still higher than 140/85, see your doctor as soon as possible. Your tablets may not be working.

- **Take your tablets every day** even if you don't feel your blood pressure is very high.
- If you have **side effects** don't stop taking your tablets – **see your GP** who may prescribe other tablets.
- You will probably have to **take tablets** and get your blood pressure checked regularly **for the rest of your life**.

There are lots of different types blood pressure tablets. Most of them are listed overleaf. **PTO**

**Diuretics (water tablets):** help get rid of excess water and salt so there is less pressure on your blood vessels.

**Beta blockers:** make your heart beat more slowly. This reduces pressure by slowing the speed of your blood flow.

**Alpha blockers:** make blood vessels wider. This reduces pressure by making more room for your blood to flow

**Calcium channel blockers:** relax blood vessels and the heart. Your blood vessels get wider and your heart beats more slowly.

**ACE inhibitors:** stop the hormone angiotensin II being produced. This helps your blood vessels expand and reduces blood flow.

**Angiotensin II receptor inhibitors:** similar to ACE inhibitors except they prevent your body using angiotensin II instead of stopping it completely. They also help your blood vessels expand and reduce blood flow.

If you **aren't happy** with your **tablets** or you think they **aren't working, speak to your doctor**. With many different types of tablet to choose from your doctor can help find the right one for you.

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#### 4. Healthy eating advice sheet

Doctors think that **what you eat** (your diet) is **linked to strokes**. Salt is linked to high blood pressure. Too much of the wrong sort of fat (saturated fat) is linked to high cholesterol and obesity.

Doctors advise you to **cut down on**:

- salt and salty foods
- **fried food & foods high in saturated fat** (red and white meat, animal fats: lard, full fat milk and cheese, cream, butter, eggs)

No one knows if eating certain foods can prevent further strokes. But by preventing or controlling the diseases which lead to strokes (high blood pressure, high cholesterol, obesity), it may help.

#### More on healthy eating:

Eating a healthy diet does not always mean eating less or giving up favourite foods. But **if you are less active** than before your stroke you may need to **cut**

**down on the amount you eat**. Dieting is not for everyone, **ask your doctor before dieting** after a stroke.

It is better to prepare your own food if you can. Supermarket meals and **tinned foods** often **contain added salt** or sugar that you are not aware of. **Check the labels** to make sure.

When you prepare food use herbs and spices for flavour instead of salt. Frying is less healthy than other ways of cooking (grilling or baking). Replace butter and animal fats with oils and margarines low in saturated fat (sunflower or olive oil products). Skimmed or semi-skimmed milk and low fat cheese are better than full fat products.

If you don't prepare your own food, **don't add extra salt** at the table. If you can't do without it, use 'Low salt' instead.

#### Healthy eating and medicine

If you have been prescribed medicine for high blood pressure or cholesterol you should keep taking it as well as changing your diet. Some people may not need both, but ask your doctor before changing or stopping your medicine.

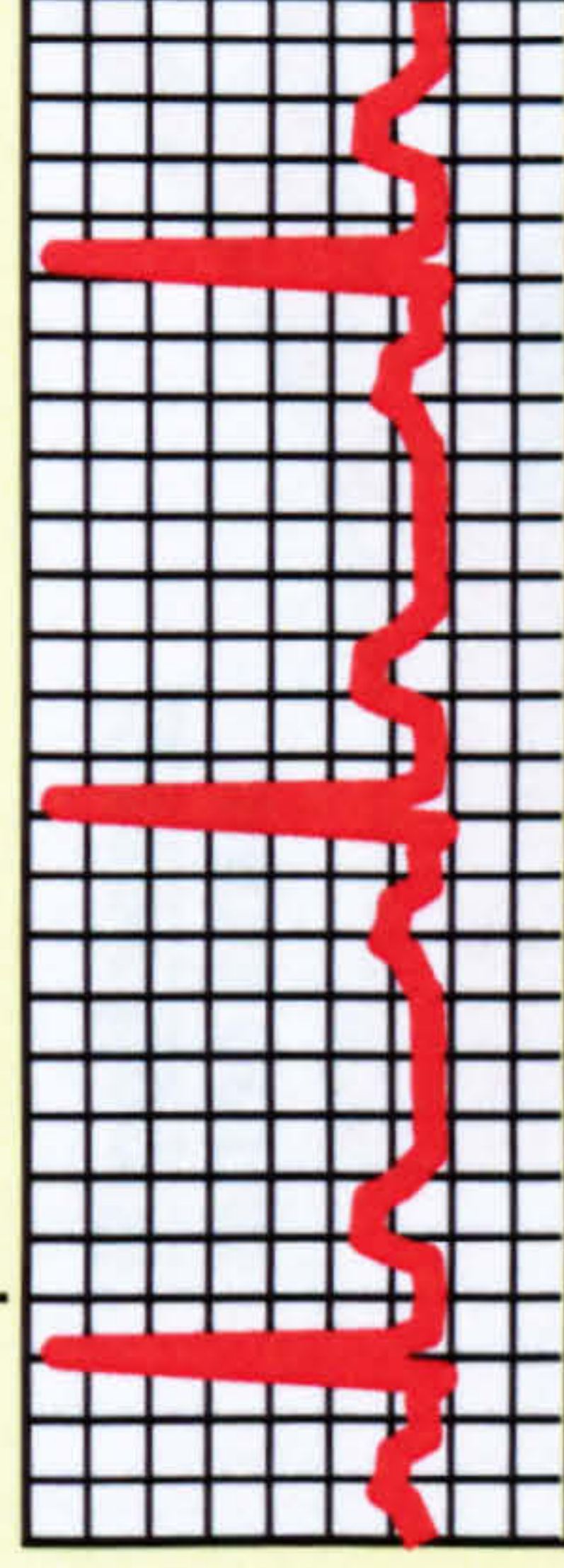
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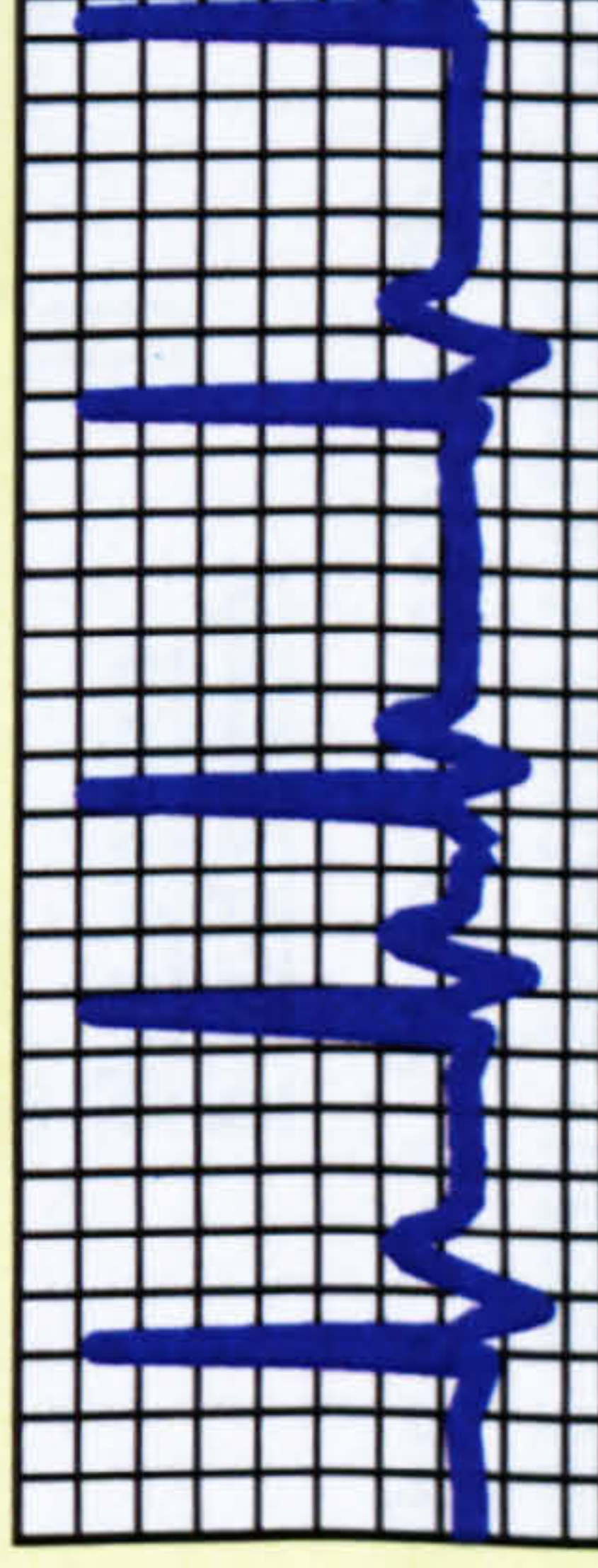
## 5. Atrial fibrillation advice sheet

You have a condition called **atrial fibrillation** (an **irregular heart beat**). Having atrial fibrillation means your heart beats **too fast** or **too slow**. An ECG test is used to measure your heartbeat.

Example of ECG test results



Normal heart:  
even gaps  
between  
heartbeats



Atrial fibrillation:  
different sized  
gaps between  
heartbeats

You may be able to feel that your heart is beating too fast or too slow. Some people have symptoms such as chest pain, palpitations, breathing problems, or feel dizzy. But even if you don't have symptoms it doesn't mean your heartbeat is OK.

Your **atrial fibrillation** may have **caused** your **stroke**. When your heart beats too fast or too slow

you have a high chance of **blood clots** forming **inside** your **heart**. If a blood clot **travels to** your **brain** it causes a stroke.

## Causes of Atrial Fibrillation

Your Atrial fibrillation may have been caused by a number of things. The most common causes are heart disease, high blood pressure, respiratory disease, infections, problems after an operation (complications), or drinking too much alcohol.

## Treatment for Atrial Fibrillation

It is very important to have your atrial fibrillation treated to prevent more strokes in the future.

Most people with atrial fibrillation are given **tablets** to make the **blood less sticky**. These **prevent clots** forming. The most common tablets are **Warfarin**. If you can't take Warfarin you may be given Aspirin, Dipyridamole or Clopidogrel instead.

The doctor may decide in some cases that you need to get the heart to beat regularly again. This can be done using tablets or by resetting the heart rhythm.

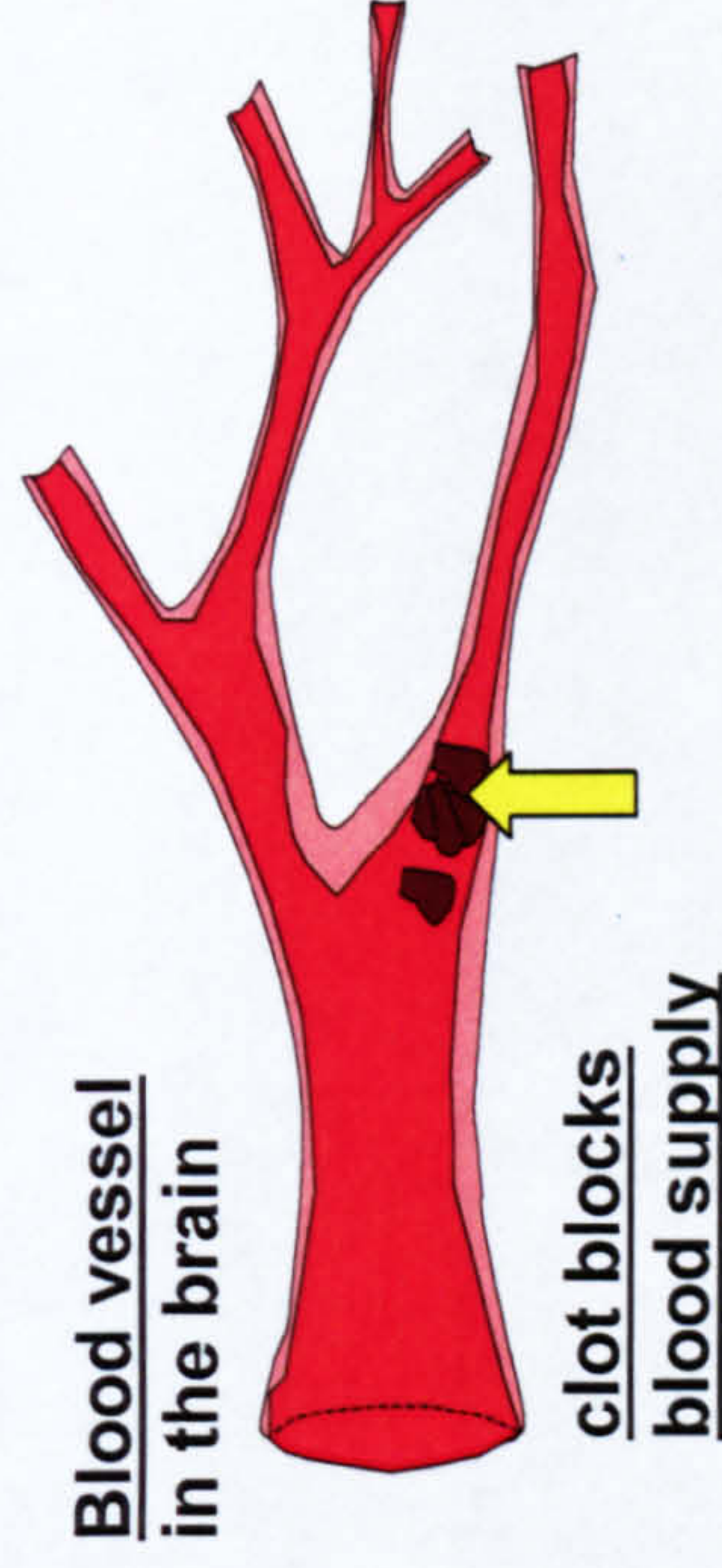
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## 6. Stroke advice sheet

### Your stroke

Your stroke was caused by a **blocked blood vessel**. If a blood **clot** gets stuck in a blood vessel it can **stop** the **blood supply** to your **brain**. This causes a **stroke**.



When the blood supply to the brain stops, parts of your **brain** become **damaged** or die. Because your brain controls the rest of your body, many different body functions can be affected (e.g. **loss** of **speech**, **weakness** in one side of the body).

### How to prevent further strokes

No one knows why your stroke happened on the day it did, but it may have been an accident waiting to happen. Blood clots are more likely to form if your

**blood vessels** are **damaged** and having a stroke is a sign that they are. They may have been damaged for many years without you even knowing about it.

Damage can be caused by **high blood pressure**, having too much **fat** (cholesterol) in your blood, **smoking** or **diabetes**. To prevent another stroke, it's important to look after these things from now on.

Most people who have had a stroke need **tablets** to make their **blood less sticky**. If your blood is less sticky, clots are less likely to form. Some of the tablets doctors prescribe are aspirin, warfarin, dipyridamole, and clopidogrel.

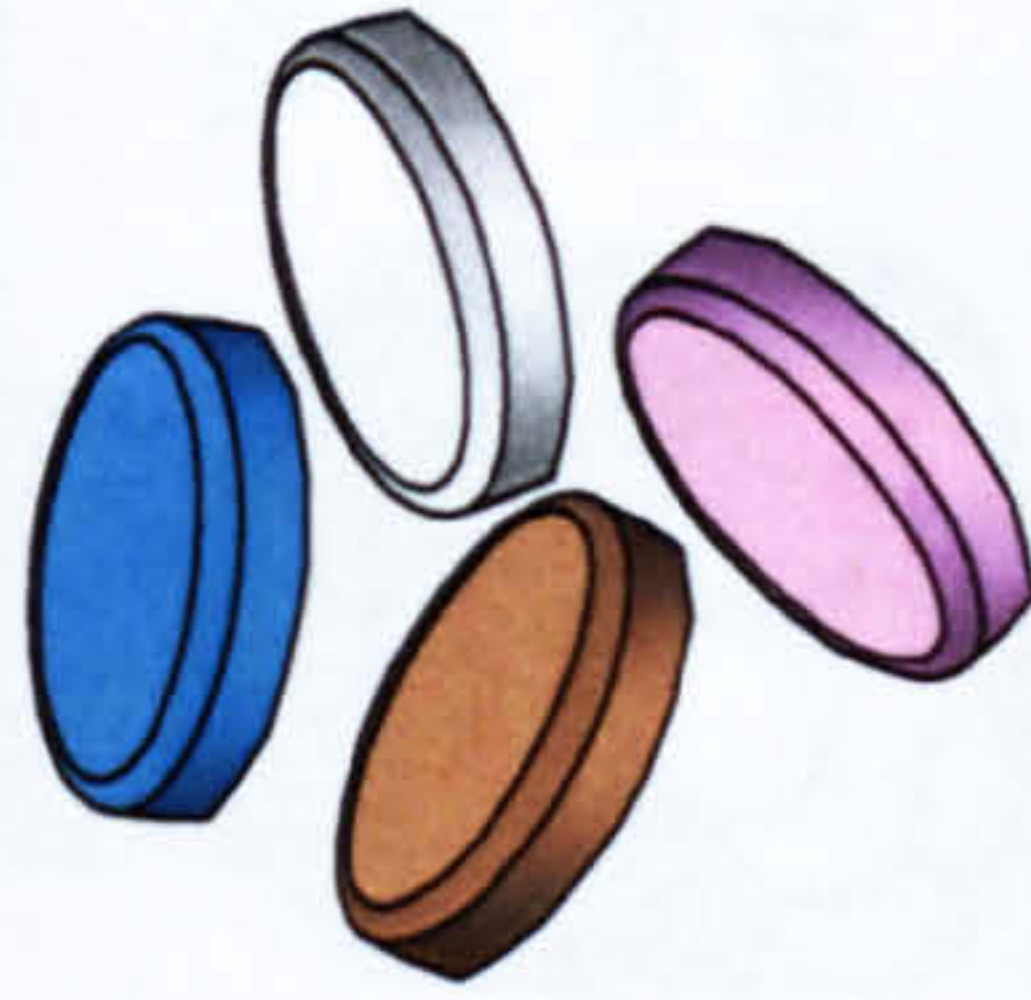
If you have **not** been **prescribed** any **tablets** make an appointment to see your **doctor** as soon as possible and ask if you need to take them. But don't start taking any new medicines (even aspirin) without seeing your doctor first.

- Keep your blood vessels healthy
- **Take your tablets** to make your blood less sticky

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## 7. Warfarin advice sheet



You have been prescribed **Warfarin** to **prevent** further **strokes**. Warfarin works by slowing down the normal clotting system in the blood. This makes your **blood less sticky** and helps **prevent clots** forming which can cause strokes.

- Take your Warfarin every day.
- If you have side effects don't stop taking your tablets – see your doctor who may change your dose or treatment.
- You may have to take Warfarin for the rest of your life.
- You will need to get your blood checked to make sure you are on the right dose (every few days at first, then every month).

It's important to **take** the **right dose** of Warfarin. If the dose is too high your clotting system could be

slowed down too much causing a **haemorrhage** (bleed). If you don't take your tablets every day it's very difficult for your doctors to find the right dose for you.

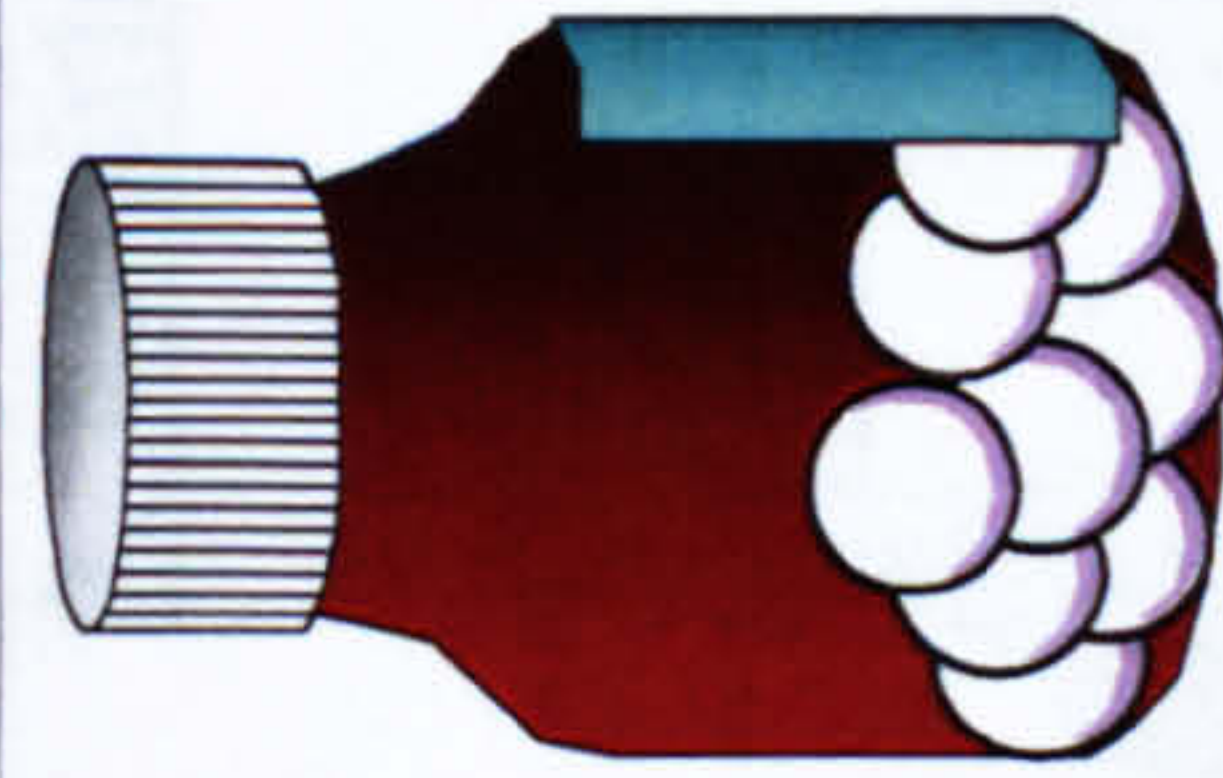
If you're not used to taking tablets, it can be hard to remember them. It's a good idea to take your Warfarin **at the same time each day** such as when you get up, go to bed, or at a certain mealtime. If you have problems talk to your GP, who may provide a **dosett box**. The box has slots for each day of the week to help you remember which tablets you have taken.

**Don't run out** of tablets. Your GP expects you to phone and **arrange a repeat prescription** before your tablets run out. If you have problems getting to the surgery to collect your prescription, phone them. They may be able to arrange for your tablets to be brought to you.

You must **tell your doctor**, dentist or chemist that **you are taking Warfarin** before you start any new tablets or medicines to make sure it's safe. Drinking a lot of alcohol on any one day (binge drinking) is also dangerous if you are taking Warfarin.

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## **8. Aspirin advice sheet**

You may have taken aspirin before (maybe for a headache). But **aspirin** can also be taken to **prevent further strokes**.

Aspirin works by slowing down the clotting system in the blood, making your **blood less sticky**. This helps prevent **blood clots** which can cause strokes.

- You should take your aspirin every day.
- Your doctor will tell you what dose you need.
- You will probably have to take aspirin every day **for the rest of your life**.

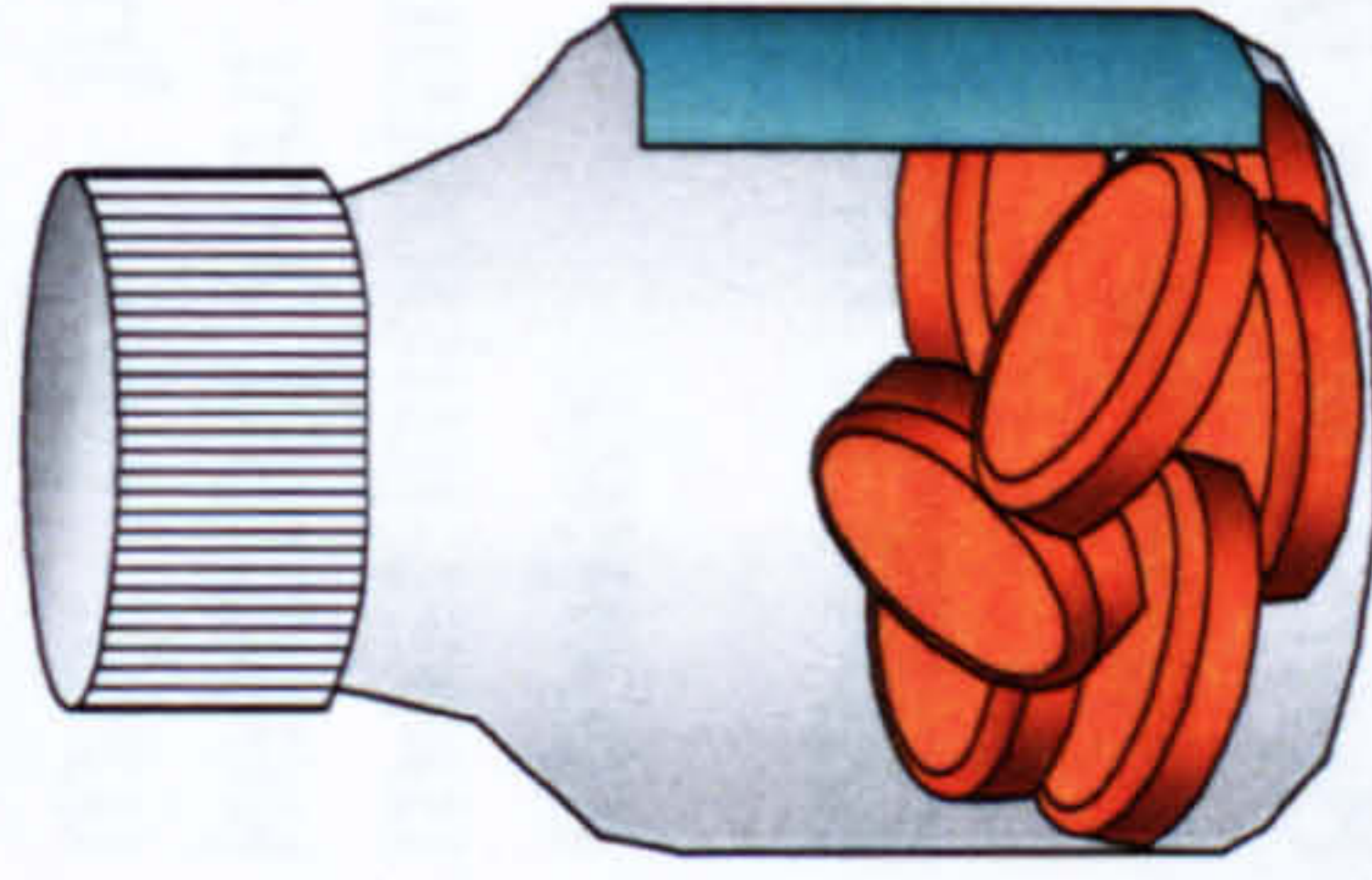
If you're not used to taking tablets, it can be hard to remember them. It's a good idea to take your aspirin **at the same time each day** such as when you get up, go to bed, or at a certain mealtime. If you have problems talk to your GP, who may provide a **dosett box**. The box has slots for each day of the week to help you remember which tablets you have taken.

**PTO**

You can get aspirin **over the counter** in a chemist or your GP can prescribe it. If you get aspirin on prescription you should phone your GP surgery to arrange a **repeat prescription** before your tablets run out.



## 9. Aspirin, dipyridamole & clopidogrel advice sheet



You have been prescribed **tablets** to help **prevent further strokes** called **antiplatelets**. The most common tablets are aspirin, dipyridamole and clopidogrel (or brand names: Persantin, Asasantin, Plavix).

These tablets work by slowing down the normal clotting system in the blood, **making** your **blood less sticky**. This helps **prevent clots**, which can cause strokes.

- Take your tablets every day.
- Your doctor will tell you what dose you need.
- If you have side effects don't stop taking your tablets – see your GP who may prescribe other tablets.
- You will probably have to take stroke tablets like these for the rest of your life.

Not all people who have had strokes need the same treatment. Some people have to take more than one type of tablet (e.g. aspirin and dipyridamole). Your doctor has prescribed the tablets that work best for you. If you have been prescribed other tablets in the past and are unsure which ones you should be taking now, speak to your GP.

If you're not used to taking tablets, it can be hard to remember them. It's a good idea to take your tablets **at the same time each day** such as when you get up, go to bed, or at a certain mealtime. If you have problems talk to your GP, who may provide a **dosett box**. The box has slots for each day of the week to help you remember which tablets you have taken.

**Don't run out** of tablets. Your GP expects you to phone and arrange a **repeat prescription** before your tablets run out. If you find it hard to get to the surgery to collect your prescription, phone them, they may be able to arrange for your tablets to be brought to you.



## 10. Diabetes advice sheet

You may have had diabetes for many years or you may have just found out that you have it. But keeping your **diabetes under control** is one of the most important things you can do to **prevent further strokes**.

### What is diabetes?

**Diabetes** is a disease that **affects** the levels of **glucose** (a type of sugar) in your blood. Normally when people eat food their body turns it into energy (glucose) using insulin. Insulin checks how much glucose you have in your blood stream. If levels are low, it tells your body to make some more. It also helps your body use the glucose it has made.

But when you have diabetes you have **problems with your insulin**. Either you don't have enough, or your body doesn't respond when the insulin tells it to make more glucose. This makes it hard for your body to turn food into energy.

### Diabetes and stroke

People who have diabetes tend to have **too much fat and cholesterol** (a fatty substance) in their

blood. Fat and cholesterol stick to your **blood vessels** causing them to be '**furred up**' or **narrowed**. This makes it harder for blood to get around the body and may lead to blood vessels becoming **blocked** causing a **stroke**.

Keeping your diabetes controlled prevents the build up of fat and cholesterol in your blood vessels and helps prevent further strokes.

### Causes and treatments

There are different types of diabetes. **Type 1 diabetes** is caused by damage to cells in the pancreas (the organ which helps digest food and makes insulin). It affects mainly young people.

**Type 2 diabetes** may be genetic. African Caribbean and Asian people are more likely to get diabetes. Being **overweight** may also increase your chance of having diabetes. Both types of diabetes need **regular check ups** by a **doctor or nurse**.

Diabetes can't be cured but it can be **controlled** with **food or medicine** (insulin injections or tablets). Your doctor will decide what treatment is best for you.

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## 11. Diabetes medicine advice sheet

You have been prescribed **medicine** for your **diabetes**. Taking it will help **prevent** another **stroke**.

- Take your diabetes medication.
- You should be careful about what you eat – follow healthy eating advice given by your doctor.
- You will probably have to take medication and follow healthy eating advice for the rest of your life.
- You may have to attend a special diabetes clinic to check your diabetes is OK.

### Diabetes tablets

You need diabetes tablets if the food alone (your diet) does not control your diabetes. There are **different types of diabetes tablet**. Some **increase** the amount of **insulin** your body makes. Some **decrease** the amount of **glucose** in your blood stream. Some stop your body turning food into glucose. And others help your body respond better

to the insulin it makes. Your doctor will find the tablets that are best for you.

### Insulin injections

If you have Type 1 diabetes you will probably already have **insulin injections**. You only need insulin injections for Type 2 diabetes if tablets and diet don't work. Injected insulin **checks glucose** and **helps the body** change glucose into energy.

If you have problems taking your medicine see your GP or diabetes doctor. **Don't run out** of medicine. Make sure you get a **repeat prescription** from your doctor before your tablets run out. Your doctor will be expecting you to arrange this. You may need a **check up** with a doctor or nurse or a **blood test** to make sure your glucose levels are OK.

If you have problems getting to the surgery to collect your prescription, phone them. They may be able to arrange for your medicine to be delivered. They may also be able to arrange for a check up to be done at home.

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## 12. Diabetes – diet advice sheet



Your **diabetes** is being **controlled** by **food** (your diet). Watching your diet is important even if you are also taking medicine.

**Everything you eat and drink affects** the **glucose** level in your blood. How often you eat also affects your glucose levels. Eating too much of the wrong sorts of food, or drinking too much alcohol affects your diabetes.

Eating **regular meals** and being careful about what you eat is one of the most important things you can do to control your diabetes. It could also **prevent another stroke**.

- You should be **careful** about what you **eat and drink** - follow healthy eating advice given by your doctor.
- You will probably have to be careful about food and drink **for the rest of your life**.
- You may have to attend a special **diabetes clinic** to check your diabetes.

**PTO**

Cutting out foods you enjoy can be hard but it is important. If you have problems sticking to your diet see your GP or diabetes doctor.



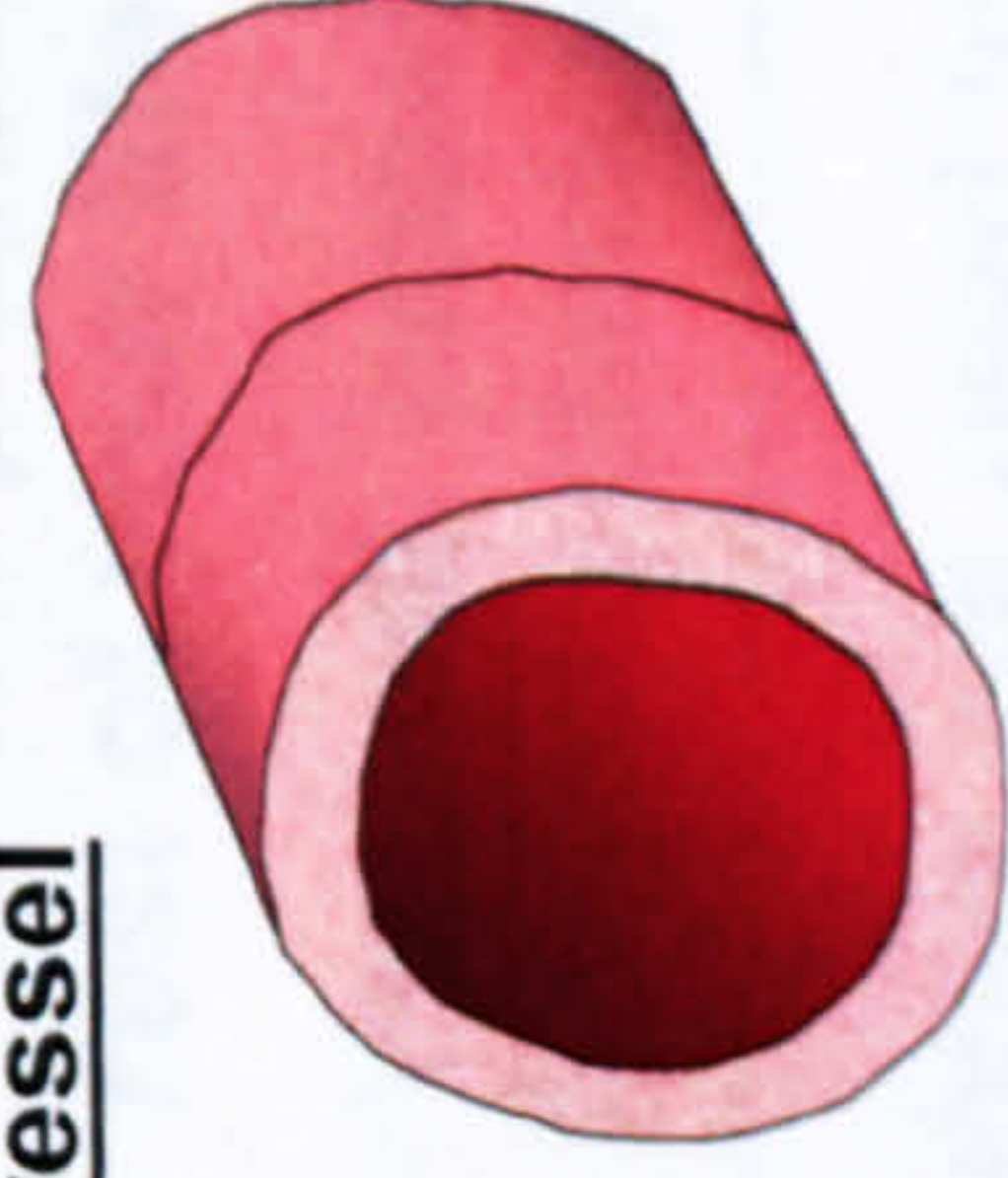
### 13. High cholesterol advice sheet

You have **high cholesterol** (a **type of fat** in the blood). Having high cholesterol means you have **too much cholesterol in your blood**. Keeping the amount of cholesterol in your blood within safe limits could help prevent further strokes.

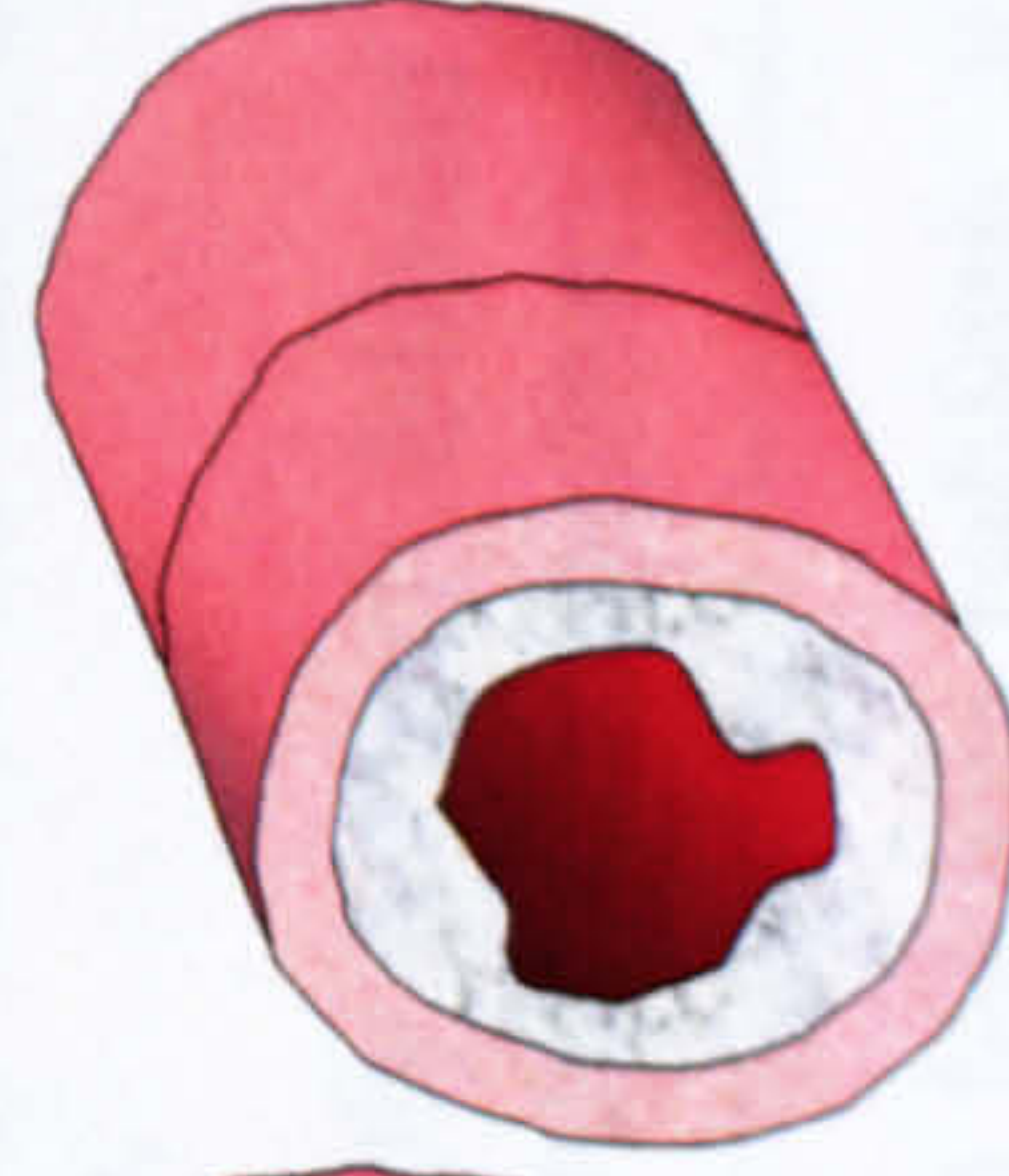
You need some cholesterol in your body for it to function properly. There are two types of cholesterol: 'good' cholesterol (high density lipoprotein HDL) and 'bad' cholesterol (low density lipoprotein LDL).

'Bad' cholesterol sticks to your **blood vessels** so they **become 'furred up' or narrowed**. This makes it more difficult for the blood to get around the body. If blood vessels become blocked it can cause further strokes.

Healthy blood vessel



Blood vessel narrowed with cholesterol



PTO

### Cholesterol causes and treatments

High cholesterol is a common problem, which **can affect anyone**. You can have high cholesterol even if you are slim and do lots of exercise.

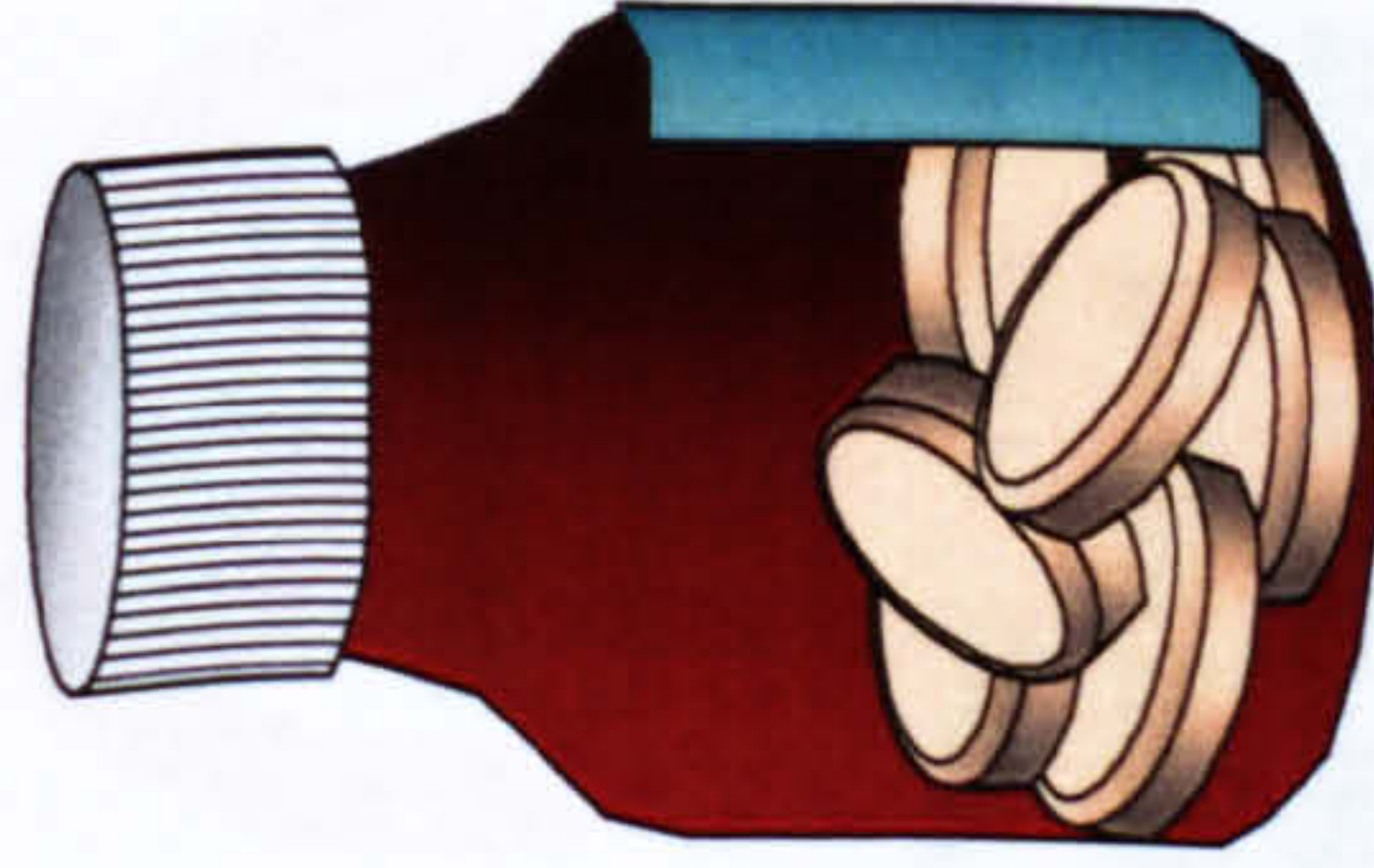
If your cholesterol is too high (**above 3.5mmol/l**) your doctor should consider **treating you with cholesterol tablets** (statins).

Apart from medicine, **cutting down on foods high in cholesterol**: red meat, animal fats and full fat dairy foods (eggs, butter, milk & cheese) can help stop your high cholesterol getting worse. **Ask your doctor or nurse** for more **advice** on how to lower your cholesterol.

You can buy special kits from your pharmacy to test your cholesterol at home. They cost around £10 but are not available on the NHS. If you would like to test your cholesterol level at home speak to your doctor about what you should buy.



## 14. Cholesterol tablet advice sheet



You have been prescribed **tablets** to **lower cholesterol** (statins). These work by lowering the amount of cholesterol in the blood. **Taking** these **tablets** will help **prevent further strokes** by keeping your cholesterol controlled.

Cholesterol tablets work by blocking your body's system for making LDL cholesterol (bad cholesterol).

- **Take** your tablets **every day**.
- If you have **side effects** don't stop taking your tablets – **see your GP** who may prescribe other treatment.
- You will probably have to take **tablets** for the **rest of your life**.
- You will probably need **blood tests** in the future to check your cholesterol.

If you're not used to taking tablets, it can be hard to remember them. It's a good idea to take your tablets

**at the same time each day** such as when you get up, go to bed, or at a certain mealtime. If you have problems talk to your GP, who may provide a **dosett box**. The box has slots for each day of the week to help you remember which tablets you have taken.

**Don't run out** of tablets. Your GP expects you to phone and arrange a **repeat prescription** before your tablets run out. If you find it hard to get to doctors' to collect your prescription, phone them, they may be able to arrange for your tablets to be brought to you.

Some people who take statins have **side effects** such as **pain or weakness** in their muscles that is not related to their stroke or to exercise. If you start to feel pain or weakness in your muscles and don't know what has caused it **see your doctor** straight away.



## 15. Smoking advice sheet



**Giving up smoking** is likely to be one of the hardest things you do. But it is also one of the most important things to **prevent further strokes**.

You may have tried giving up before and not managed it, but it's worth trying again. Giving up smoking now will help prevent further strokes even if you have been a smoker for years. **It's never too late to quit.**

- Giving up smoking **will make a difference** even if you have been a smoker for years.
- **Nicotine patches** and **gum** can improve your chances of success.

### Smoking and stroke

Smoking can lead to strokes because it **causes** your **blood vessels to become 'furred' or narrowed**. If your blood vessels become **blocked** this can **cause a stroke**. Cigars and pipes may not be as bad for you as cigarettes but they are also linked to strokes.

If you really can't give up, **cut down**. Cutting down is **better than nothing** and will also help prevent further strokes.

### Helping you quit

**Nicotine patches** and **gum** give your body the nicotine it **craves** when you give up smoking, but without causing damage to your health.

Some people are afraid of getting **addicted** to patches or gum. But patches and gum are easier to give up than cigarettes, and also don't cause strokes! You may be able to get patches and gum on **prescription** (speak to your **GP**). Don't use nicotine patches or gum while you are still smoking.

**Giving up** smoking can be even more **difficult** if your family and friends are also smokers. **Support** from **family and friends** is **vital** to help you quit, so now is a good time for them to give up smoking too.

Some people join a group to help them quit. A **group** can provide **advice** and **support**. If you would like to join a group ask your GP about local groups or clinics.

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## 16. Alcohol advice sheet for men

For most people, drinking **alcohol** is OK. But that depends on how much you drink. Doctors have set limits on the amount you can drink each day. Drinking more than these limits (**heavy drinking** or **binge drinking**) could lead to another **stroke**.

Doctors advise you **not** to drink **more than**:

- **1-2 pints** of normal strength **beer** or lager a day  

- OR
- **3-4 small glasses** of **wine** a day (half bottle)  

- OR
- **3-4 single** measures of **spirits** a day (whisky, gin, vodka etc.)  


You don't need to give up unless you want to. But, do be careful about how much you drink even if you have been a drinker for many years and can drink quite a lot.

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## 17. Alcohol advice sheet for women

For most people, drinking **alcohol** is OK. But that depends on how much you drink. Doctors have set limits on the amount you can drink each day. Drinking more than these limits (**heavy drinking** or **binge drinking**) could lead to another **stroke**.

Doctors advise you **not** to drink **more than**:

- **2-3 half pints** of **beer** or lager a day (3-4 cans)  

- OR
- **2-3 small glasses** of **wine** a day (third of a bottle)  

- OR
- **2-3 single** measures of **spirits** a day (whisky, gin, vodka etc.)  


You don't need to give up unless you want to. But, do be careful about how much you drink even if you have been a drinker for many years and can drink quite a lot.

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## 18. Obesity advice sheet

Losing weight is likely to be one of the hardest things you have to do but being **obese** is **dangerous** to your **health**. Clinical obesity is not the same as being a bit overweight. No one knows if your stroke was caused by your obesity. But people who are obese are more likely to have health problems including **heart disease**, **diabetes** and **strokes**.

If you can **lose** even a bit of **weight**, this will benefit your health and may help **prevent further strokes**.

- You should ask your **doctor** whether you need **treatment** for obesity
- You may need to see an expert in treating obesity (such as a **dietician**)

### Treatment:

Treatment includes **dieting**, increasing **exercise**, psychological **therapy**, **drug** treatment and **surgery**. Most people need to combine more than one treatment. A **doctor** or **dietician** can advise you on the best treatment for you.

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If you have tried going on a diet or doing exercise before and it didn't work, ask your **doctor** for advice on what to do next.

Even if you do have other treatments, you will probably need to change **eating** and **exercise** habits to **maintain weight loss**. You will need to watch your weight for the **rest of your life**.



## 19. Exercise advice sheet

Doctors think that there is a **link** between **how active/fit** you are (how much exercise you do) and strokes. Lack of exercise can lead to **some diseases**, which can **lead to strokes** (e.g. high blood pressure, diabetes, high cholesterol and obesity).

After a stroke, doctors advise that you should:

- **do regular exercise** (even if you can't walk very far at the moment)
- **build up** the amount of exercise you do **slowly**

No one knows if **being more active** will prevent further strokes, but it will make you fitter. This can help **prevent** or **control diseases**, which lead to strokes.

### What is regular exercise?

Taking **regular exercise** does not have to mean going to a gym or being 'sporty'. The secret is to choose **something you enjoy**, and something that

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fits in with your daily routine (e.g. **walking** counts as exercise).

Doctors advise you should try to exercise for **30 minutes every day** (at least 5 time a week). You don't have to do all the exercise in one go. You could do **two lots of 15 minutes** instead of one 30 minute slot. Its OK if you can only walk for a couple of minutes and then need to rest. You can **build up slowly**.

A lot of people find it **difficult** to be active **after a stroke** and need help getting around. You don't have to leave the house to start walking. Ask your doctor about ways to get fitter.

### Sports and exercise:

If you are used to doing exercise in a gym or with a group that is OK too. But **check** with your **doctor** to make sure. Always check with your doctor before starting **new exercise**.

**Different Strokes** is a charity for young people who have had a stroke. They run special exercise classes. Ask your **doctor** about local **exercise groups** or services for people who've had strokes.

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## 20. Blood pressure advice sheet

Looking after your **blood pressure** is one of the most important things you can do to help **prevent further strokes**.

In the past doctors only worried about blood pressure if it was very high. Nowadays, doctors think that keeping your blood pressure as **low as possible** can help prevent further strokes, even if it has never been high in the past.

### **3 ways to look after your blood pressure:**

- Get your blood pressure **checked** by your doctor at least **every 6 months**
- **Take your blood pressure tablets** (if you have been prescribed them by a doctor)
- Watch what you eat, **cut down on salt** and foods high in salt

### **Blood pressure treatment**

Blood pressure can be lowered with **tablets**, but not everyone needs them. Your doctor will decide what treatment is best for you.

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**Cutting down on salt** also helps lower your blood pressure and may stop you needing tablets in the future.

### **Blood pressure checks**

Blood pressure machines give you two numbers. The first is the pressure when your blood is pumped out of the heart. The second is the pressure when your heart is relaxed. Doctors say your blood pressure should be **no higher than 140/85**, but **the lower the better**.

You should get your blood pressure **checked** at least **every 6 months**. If it is not controlled you may need to see your GP more often. If you haven't had your blood pressure checked since your stroke, make an appointment to get it checked by a doctor or nurse as soon as possible.

You can buy kits to test your blood pressure at home (from large chemists) but they aren't cheap (about £100) and are not available on the NHS. If you want to buy one, ask your doctor for advice.

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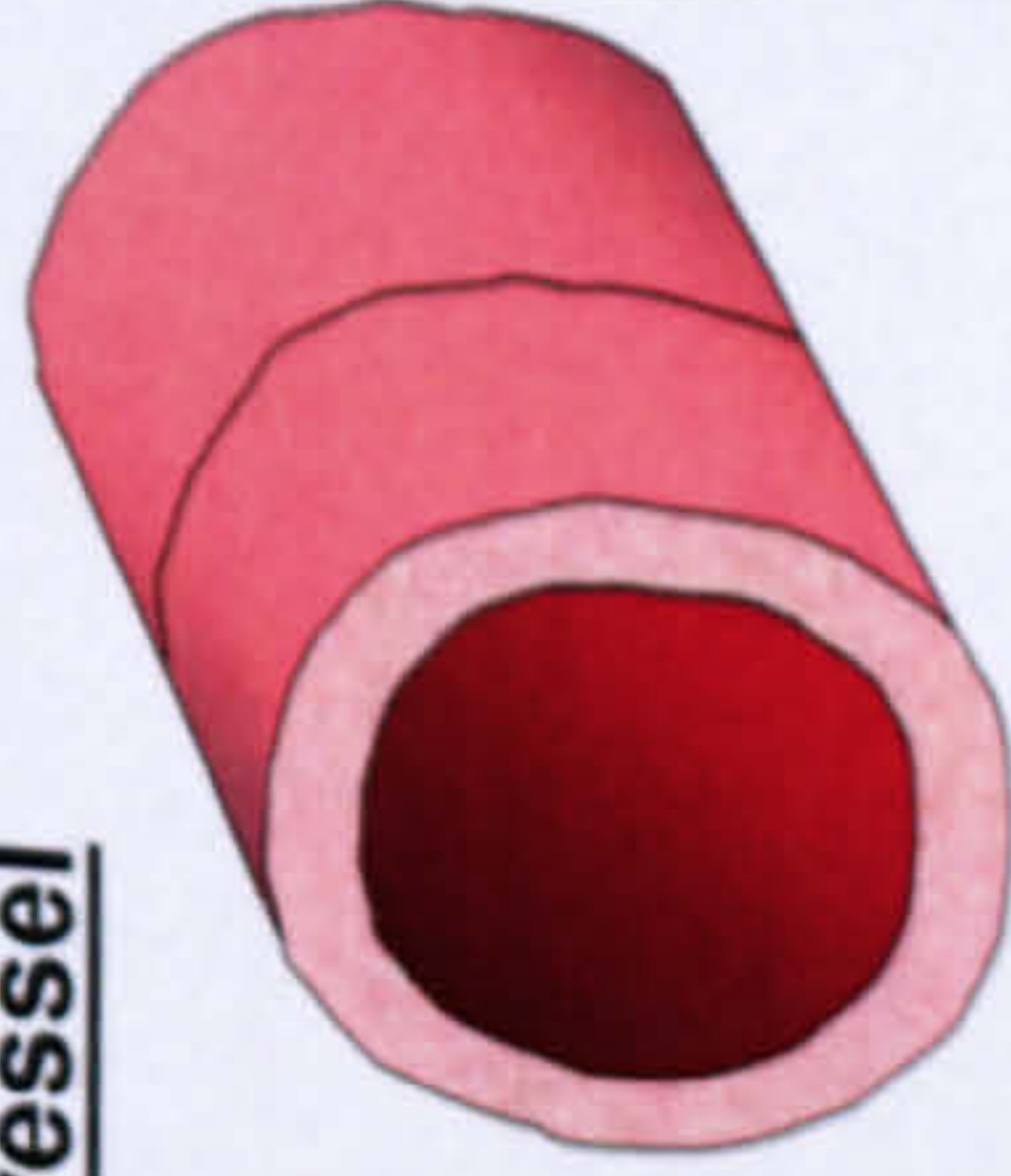
## 21. Cholesterol advice sheet

**Cholesterol** is a **type of fat** that exists in your blood. Keeping the amount of cholesterol in your blood as **low as possible** could help **prevent further strokes**.

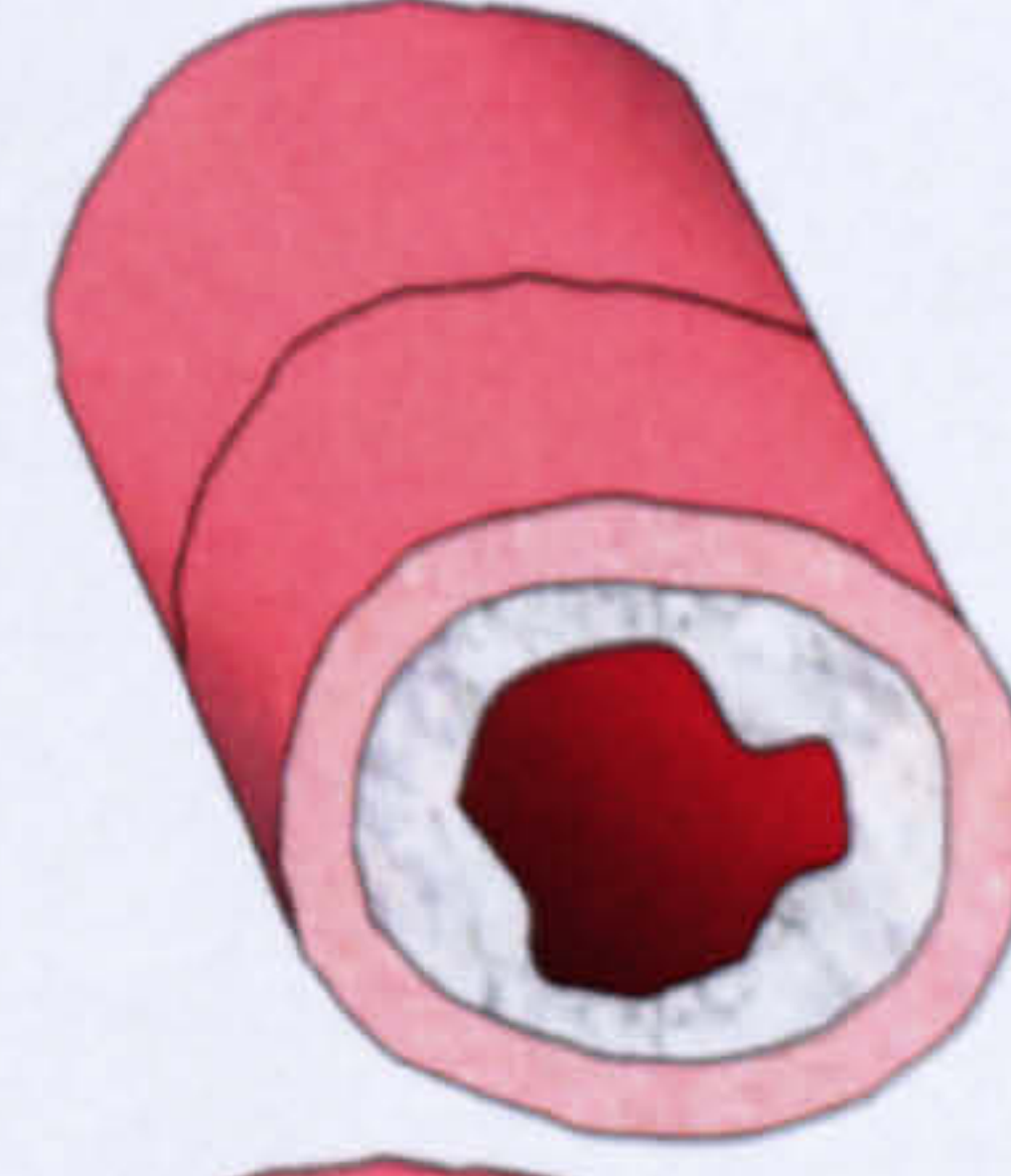
You need some cholesterol in your body for it to function properly. There are two types of cholesterol: 'good' cholesterol (high density lipoprotein HDL) and 'bad' cholesterol (high density lipoprotein LDL).

Bad cholesterol sticks to your **blood vessels** so they become '**furred up**' or narrowed. This makes it more difficult for the blood to get around the body. If the blood vessels become too narrow blood they can become **blocked** which can lead to **further strokes**.

Healthy blood vessel



Blood vessel narrowed with cholesterol



In the past doctors only worried about cholesterol if it was very high. Nowadays they think you should keep your **cholesterol** as **low as possible**. This is important even if it has never been very high and even if you are slim and do lots of exercise.

### Cholesterol tests and treatment

Cholesterol tests tell you how much cholesterol you have in your blood. Your cholesterol should be no higher than 3.5mmol/l, but the lower the better. If you have never had a **cholesterol test** speak to your doctor who can arrange one for you.

Cholesterol can be lowered with **tablets** (statins), but not everyone needs them. Your doctor will decide whether you need treatment.

Apart from tablets, **cutting down on foods high in cholesterol**: red meat, animal fats and full fat dairy foods (eggs, butter, milk & cheese) can help stop cholesterol getting worse. **Ask your doctor or nurse** for more **advice** on how to lower your cholesterol.

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## **Appendix 10. Papers arising from this thesis.**

### **Peer reviewed journal articles:**

1. Redfern J, McKevitt C, Wolfe CDA. Complex interventions in stroke care: a systematic review. *Stroke* 2006; 37:2410-2419.
2. Redfern J, McKevitt C, Wolfe CDA. Risk Management After Stroke: The limits of a patient-centred approach. *Health, Risk and Society* 2006; 8: 123-141.
3. McKevitt C, Redfern J, Mold F, Wolfe CDA. Qualitative Studies of Stroke: A Systematic Review. *Stroke* 2004; 35: 1499-1505.
4. Redfern J, McKevitt C, Rudd A, Wolfe CDA. Health care after stroke: opportunities for secondary prevention. *Family Practice* 2002; 19: 378-382.
5. Redfern J, McKevitt C, Dundas R, Rudd A, Wolfe CDA. Behavioural risk factors and lifestyle change following stroke: a prospective study. *Stroke*, 2000; 31:1877-1881.

### **Book chapters:**

6. Redfern, J, McKevitt, C, Rudd, A, Wolfe, CDA. Review of interventions to change patient and professional behaviors in stroke management and prevention. In *Best Practices in the Behavioral Management of Chronic Disease*. J Trafton and WP Gordon (Eds). California: Institute for Brain Potential; updated 2006.



## **Appendix 11. Presentations arising from this thesis**

### **Published Abstracts:**

1. Redfern J, McKevitt C, Wolfe C. Improving the development and evaluation of complex interventions in stroke prevention and management - beyond guesswork. *Cerebrovascular Diseases*; 2006; 21: 122.
2. Redfern J, McKevitt C, Wolfe C. The MRC Framework for developing and evaluating complex interventions: putting theory into practice. *Journal of Epidemiology and Community Health*, 2004; 58: A2.
3. McKevitt C, Redfern J, Mould F, Wolfe C. What do qualitative studies of stroke tell us? A literature review. *Cerebrovascular diseases*, 2003; 16: 110.
4. Redfern J, McKevitt C, Rudd A, Wolfe C. A pilot evaluation of a new secondary prevention intervention: lessons for current practice. *Cerebrovascular diseases*, 2003; 16:98.
5. Redfern J, McKevitt C., Wolfe C. Developing a secondary prevention intervention: the limits of evidence-based guidelines. *Cerebrovascular diseases*, 2002; 12: 20
6. Redfern J, McKevitt C., Wolfe C. Communicating secondary prevention advice: a qualitative investigation of current practice. *Cerebrovascular diseases*, 2001; 11, 15.
7. Redfern J, McKevitt C, and Wolfe C. Facilitating risk factor change after stroke. A qualitative study of patient's perspectives. *Cerebrovascular Diseases*, 2000; 10: 2.

### **Other conference presentations:**

1. Redfern, J. Methods for developing and evaluating complex interventions. Paper presented at the King's College London School of Biomedicine & Health Sciences and School of Medicine Postgraduate Research Symposium. London; 2006.
2. Redfern J, Frisby L, McKevitt C, Montoute K, Coshall C, Rudd A, Wolfe C. Stop Stroke The South London Secondary Prevention Programme: a cluster randomised controlled trial of a novel intervention to prevent stroke recurrence. Paper presented at the 14<sup>th</sup> European Stroke Conference, Bologna; 2005.

3. Redfern J, McKevitt C, Frisby L, Montoute K, Rudd A, Wolfe C. Stop Stroke The South London Secondary Prevention Programme: evaluation of a multifaceted secondary prevention programme for stroke. Paper presented at the 13<sup>th</sup> European Stroke Conference, Mannheim; 2004.
4. Redfern J, McKevitt C, Wolfe C. Representing recurrence risk to stroke patients. A qualitative study of risk factor control in the stroke clinic. Paper presented at the Society for Social Medicine 48<sup>th</sup> Annual Scientific Meeting, Birmingham; 2004.
5. Redfern J, McKevitt C, Wolfe C. How objective is risk estimation and management? A qualitative study of risk factor control in the stroke clinic. Paper presented at the Pathways for Research Cardiovascular Risk Factors Conference, Southwark; 2004.
6. Redfern J, McKevitt C, Wolfe C. Stroke secondary prevention: organisational barriers in the stroke clinic. Paper presented at the Pathways for Research Cardiovascular Risk Factors Conference, Southwark; 2004.
7. Redfern J, McKevitt C, Wolfe C. How objective is risk estimation and management? A qualitative study of risk factor control in the stroke clinic. Paper presented at the 5<sup>th</sup> World Stroke Congress, Vancouver; 2004.
8. Redfern J, McKevitt C, Wolfe C. Stroke secondary prevention: organisational barriers in the stroke clinic. Paper presented at the 5<sup>th</sup> World Stroke Congress, Vancouver; 2004.
9. Redfern J, McKevitt C, Frisby L, Montoute K, Rudd A, Wolfe C. Stop Stroke: A new intervention to improve stroke secondary prevention. Paper presented at the 8<sup>th</sup> Stroke Association Scientific meeting Birmingham; 2003.
10. Redfern J, McKevitt C, Wolfe C. "Keep your risk factors under control!" Communicating secondary prevention to stroke patients. Paper presented at the 10<sup>th</sup> British Sociological Society Medical Sociology Group Meeting, York; 2001.
11. Redfern J, McKevitt C, Wolfe C. Communication and delivery of secondary prevention advice: a qualitative investigation of current practice. Paper presented at the 6<sup>th</sup> Stroke Association Scientific Meeting, Oxford; 2001.
12. Redfern J, McKevitt C, Rudd A, Wolfe C. Preventing stroke recurrence: the Stop Stroke project. Paper presented at the East London & City Hypertension prevention conference, London; 2001.
13. Redfern J, McKevitt C, Wolfe C. Barriers to implementing secondary prevention. Royal College of Physicians Clinical effectiveness Unit, London Regional Workshop; 2001.
14. Redfern J, McKevitt C, Wolfe C. Ethnic differences in lifestyle and the process of risk factor change following stroke. Paper presented at the Centre for Caribbean Medicine Annual Conference; London, 2000.



15. Redfern J, McKevitt C, Wolfe C. Management of risk factors and health service use following stroke. Paper presented at the Society for Social Medicine 44<sup>th</sup> Annual Scientific Meeting, Norwich; 2000.
16. Redfern J, McKevitt C, Wolfe C. Ethnic differences in risk factors following stroke. Paper presented at the Royal Society of Medicine Ethnicity, Ageing and Health Conference, London; 2000.
17. Redfern J, McKevitt C, Wolfe C. Ethnicity and the process of risk factor change following stroke: A qualitative study. Royal Society of Medicine, Ethnicity, Ageing and Health Conference, London; 2000.